

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

Filed: January 23, 2024

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BASEM ALSAADEH,	*	PUBLISHED
	*	
Petitioner,	*	No. 19-1097V
	*	
v.	*	Special Master Nora Beth Dorsey
	*	
SECRETARY OF HEALTH	*	Dismissal; Pneumococcal Conjugate
AND HUMAN SERVICES,	*	("Pneumovax 23") Vaccine; Influenza ("Flu")
	*	Vaccine; Hearing Loss; Autoimmune Inner
Respondent.	*	Ear Disease ("AIED"); Sensorineural
	*	Hearing Loss ("SNHL").
* * * * *		

Brian L. Cinelli, Schiffmacher Cinelli Adoff LLP, Buffalo, NY, for Petitioner.  
Neil Bhargava, U.S. Department of Justice, Washington, DC, for Respondent.

### DECISION<sup>1</sup>

On July 30, 2019, Basem Alsaadeh ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 *et seq.* (2018),<sup>2</sup> alleging that he suffered from hearing loss as a result of receiving an influenza ("flu") vaccine and a pneumococcal conjugate ("Pneumovax 23") vaccine on October 22, 2016. Petition at ¶ 1 (ECF No. 1). Respondent argued against compensation, stating "this case is not appropriate for compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 25).

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<sup>1</sup> Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc> in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

After carefully analyzing and weighing the evidence presented in accordance with the applicable legal standards, the undersigned finds Petitioner has failed to provide preponderant evidence that the flu and/or Prevnar 13 vaccines he received caused his hearing loss. Thus, Petitioner has failed to satisfy his burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, the petition must be dismissed.

## **I. ISSUES TO BE DECIDED**

“The parties do not dispute that Petitioner suffered hearing loss.” Joint Submission, filed Dec. 5, 2022, at 2 (ECF No. 66). However, Respondent questions whether the diagnosis is autoimmune inner ear disease (“AIED”), as suggested by Petitioner’s expert. Resp. Brief on Entitlement (“Resp. Br.”), filed Mar. 22, 2023, at 11-12 (ECF No. 72).

The parties dispute causation. Particularly, “[t]he parties dispute whether Petitioner’s hearing loss was caused by the subject vaccinations and whether Petitioner has satisfied the Althen prongs.” Joint Submission at 2. Petitioner contends he has met his burden under the Althen criteria. Petitioner’s (“Pet.”) Br., filed Dec. 5, 2022, at 14-25 (ECF No. 65). Respondent disagrees and argues Petitioner failed to preponderantly establish that his hearing loss was caused-in-fact by his vaccinations. Resp. Br. at 14.

## **II. BACKGROUND**

### **A. Medical Terminology**

AIED is an “autoimmune process that leads to the dysfunction of the inner ear, resulting in fluctuating, audiovestibular symptoms.” Pet. Exhibit (“Ex.”) 19-5 at 1.<sup>3</sup> AIED is associated with sensorineural hearing loss (“SNHL”).<sup>4</sup> See Pet. Ex. 18-4 at 13 tbl.7, 16.<sup>5</sup> “AIED is considered to be responsible for [less than] 1% of all SNHL cases.” Pet. Ex. 18-9 at 1.<sup>6</sup>

“The clinical expression of AIED is a progressive bilateral and not always symmetric SNHL, progressively developing between [three] and 90 days, which typically benefits from [] steroid and immunosuppressive therapy.” Pet. Ex. 18-9 at 1. Often only one ear is affected in

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<sup>3</sup> Hitomi Sakano & Jeffrey P. Harris, Emerging Options in Immune-Mediated Hearing Loss, 4 Laryngoscope Investigative Otolaryngology 102 (2019). This is also cited as Resp. Ex. A, Tab 5.

<sup>4</sup> SNHL is defined below. See *infra* page 3.

<sup>5</sup> Sujana S. Chandrasekhar et al., Clinical Practice Guidelines: Sudden Hearing Loss (Update), 161 Otolaryngology Head & Neck Surgery s1 (2019).

<sup>6</sup> Andrea Ciorba et al., Autoimmune Inner Ear Disease (AIED): A Diagnostic Challenge, 32 Int’l J. Immunopathology & Pharmacology 1 (2018).

the early stage. Id. at 3. “The hearing deficit sometimes presents threshold fluctuations.” Id. “[T]he presence of bilateral SNHL of 30dB or more at any frequency with evidence of progression in at least one ear on two serial audiograms performed less than [three] months apart” is the presentation often used for diagnosis. Pet. Ex. 18-11 at 2.<sup>7</sup> In 25-50% of cases, tinnitus<sup>8</sup> can be present. Pet. Ex. 18-9 at 3. Importantly, “there are no standardized diagnostic criteria or reliable diagnostic tests for the diagnosis of AIED.” Id. at 1. As such, the diagnosis of “immune-mediated cochleovestibular disorders” is based on clinical symptoms, lab tests (“demonstrating the presence in the serum of antibodies or activated T cells against inner ear antigens”), and on the response to immunosuppressive treatment. Id. at 3. “Essentially, AIED is a diagnosis of exclusion, suspected in case of a documented progressive SNHL, when other etiologic causes have been ruled out.” Id.

SNHL is “hearing loss due to a lesion in either the cochlea (sensory mechanism of the ear), the vestibulocochlear nerve, the central neural pathways, or a combination of these structures.” Sensorineural Hearing Loss, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=80207> (last visited Nov. 17, 2023). It results from either damage to the cochlea or “disruption of the electrical conduction pathway from the inner ear to the brain. Thus, injury to hair cells, supporting cells, auditory neurons, or the central auditory pathway can cause [SNHL].” Anil K. Lalwani, Disorders of Hearing, in 1 Harrison’s Principles of Internal Medicine 238, 240 (Joseph Loscalzo et al. eds., 21st ed. 2022). Damage to the hair cells may be caused by intense noise, viral infections, Meniere’s disease,<sup>9</sup> or aging. Id.

Conductive hearing loss is “hearing loss due to a defect of the sound-conducting apparatus, i.e., of the external auditory canal<sup>[10]</sup> or middle ear.”<sup>11</sup> Conduction Hearing Loss, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=>

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<sup>7</sup> Tamara Mijovic et al., Autoimmune Sensorineural Hearing Loss: The Otology-Rheumatology Interface, 52 Rheumatology 780 (2013).

<sup>8</sup> Tinnitus is “a noise in the ears, such as ringing, buzzing, roaring, or clicking. It is usually subjective in type.” Tinnitus, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=50114> (last visited Nov. 17, 2023).

<sup>9</sup> Meniere’s disease is “hearing loss, tinnitus, and vertigo resulting from nonsuppurative disease of the labyrinth with edema.” Meniere Disease, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=70588> (last visited Nov. 17, 2023).

<sup>10</sup> The external auditory canal is “the passage of the external ear leading to the tympanic membrane, divided into an outer cartilaginous meatus and an inner bony meatus.” Meatus Acusticus Externus, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=88271> (last visited Nov. 17, 2023).

<sup>11</sup> The middle ear is “the cavity in the temporal bone comprising the cavitas tympani, auditory ossicles, and tuba auditiva.” Auris Media, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=59682> (last visited Nov. 17, 2023).

80188 (last visited Nov. 17, 2023). “Factors that obstruct the transmission of sound or dampen the acoustic energy result in conductive hearing loss.” Lalwani, supra, at 239. Conductive hearing loss can occur from obstruction of the external auditory canal by earwax, debris, and foreign bodies; swelling or narrowing of the lining of the canal; neoplasms of the canal; perforations of the tympanic membrane;<sup>12</sup> disruption of the vibration transmissions by trauma or infection; or fluid, scarring, or neoplasms in the middle ear. Id.

## **B. Procedural History**

Petitioner filed his petition on July 30, 2019. Petition. That same day, Petitioner filed medical records,<sup>13</sup> medical literature, an affidavit, and a declaration<sup>14</sup> by his treating ear nose and throat (“ENT”) physician, Dr. Deborshi Roy. Pet. Exs. 1-12. Respondent filed his Rule 4(c) Report arguing against compensation on August 10, 2020. Resp. Rept. at 1.

On April 30, 2021, Petitioner filed an expert report from Dr. Richard Beck. Pet. Ex. 18. On August 27, 2021, Respondent filed expert reports from Dr. J. Lindsay Whitton and Dr. Douglas C. Bigelow. Resp. Exs. A, C. Petitioner filed a supplemental expert report from Dr. Beck on December 29, 2021, and Respondent filed supplemental expert reports from Dr. Whitton and Dr. Bigelow on April 29, 2022. Pet. Ex. 19; Resp. Exs. E-F.

The undersigned held a Rule 5 conference on June 2, 2022. Order dated June 2, 2022 (ECF No. 48). However, the undersigned was unable to give her preliminary findings and opinions “due to the complexities regarding the alleged mechanism of causation and the factual issues of onset and type of hearing loss.” Id. at 1. Given the risk to both sides, the parties were encouraged to initiate settlement negotiations. Id. Petitioner provided a demand to Respondent, but upon review, Respondent elected to continue to defend the case. Pet. Status Rept., filed July 18, 2022 (ECF No. 49); Joint Status Rept., filed Sept. 20, 2022 (ECF No. 58). The parties agreed to resolve entitlement through a ruling on the record. Joint Status Rept., filed Sept. 20, 2022.

On December 5, 2022, Petitioner filed his brief for a ruling on the record. Pet. Br. Respondent filed his brief on March 22, 2023. Resp. Br. On April 24, 2023, Petitioner filed a reply. Pet. Reply to Resp. Br. (“Pet. Reply”), filed Apr. 24, 2023 (ECF No. 73).

This matter is now ripe for adjudication.

## **C. Factual History**

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<sup>12</sup> The tympanic membrane, also called the eardrum, is “the obliquely placed, thin membranous partition between the external acoustic meatus and the tympanic cavity.” Membrana Tympanica, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=88565> (last visited Nov. 17, 2023).

<sup>13</sup> Petitioner continued to file medical records throughout the course of litigation.

<sup>14</sup> This exhibit is titled “Affidavit,” but it is not notarized, and therefore the undersigned references it as a declaration.

## 1. Stipulated Facts

The parties agreed to the following stipulated facts as set forth in their Joint Submission. See Joint Submission at 1-2.

Petitioner was born on August 1, 1958. Joint Submission at 1 (citing Pet. Ex. 1 at ¶ 2). He received his medical degree in his native country of Jordan, and trained in internal medicine, hematology, oncology, and hyperbaric medicine. Id. (citing Pet. Ex. 1 at ¶ 2). He subsequently moved to the United States and currently resides in California. Id. (citing Pet. Ex. 1 at ¶ 3).

On October 22, 2016, Petitioner received the quadrivalent flu vaccination and Prevnar 13 vaccination intramuscularly in his left deltoid. Joint Submission at 1 (citing Pet. Ex. 2 at 1).

About one week later, Petitioner developed symptoms similar to an upper respiratory infection (“URI”) and then noticed problems hearing. Joint Submission at 2 (citing Pet. Ex. 1 at ¶ 7). In November 2016, Petitioner began taking a 10-day course of amoxicillin and a three-day course of Zithromax,<sup>15</sup> two antibiotics which he had in his possession and took at his own direction as a physician. Id. (citing Pet. Ex. 1 at ¶ 7). Petitioner’s “symptoms continued to progress over the following weeks and at the end of December 2016, he began taking a course of the antibiotic [levofloxacin].”<sup>16</sup> Id. (citing Pet. Ex. 1 at ¶ 8).

On March 2, 2017, Petitioner presented to Redlands Community Hospital and saw Lauren Lo, nurse practitioner (“NP”). Joint Submission at 2 (citing Pet. Ex. 3 at 38). Petitioner “reported his symptoms and asked to have his testosterone checked because he was feeling fatigue[d].” Id. (citing Pet. Ex. 3 at 38).

## 2. Summary of Medical Records

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<sup>15</sup> Zithromax is trademark for azithromycin. Zithromax, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=54062> (last visited Nov. 17, 2023). Azithromycin is “an azalide antibiotic . . . that inhibits bacterial protein synthesis, effective against a wide range of gram-positive, gram-negative, and anaerobic bacteria; used in the treatment of mild to moderate infections caused by susceptible organisms.” Azithromycin, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=5244> (last visited Nov. 17, 2023).

<sup>16</sup> Levofloxacin is “a broad-spectrum fluoroquinolone antibacterial agent used in the treatment of infection by susceptible organisms, including bronchitis, community-acquired pneumonia, pyelonephritis, urinary tract infections, acute maxillary sinusitis, and skin and soft tissue infections.” Levofloxacin, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=28157> (last visited Nov. 17, 2023).

In addition to the facts stipulated to by the parties, the following summary of medical records provides additional relevant information.

Prior to the vaccinations at issue, Petitioner had a history of type II diabetes mellitus, vitamin D deficiency, hypertension, hyperlipidemia, and coronary artery disease. Pet. Ex. 3 at 1-3, 32. At an appointment with his primary care physician (“PCP”) on September 29, 2016, three weeks prior to the vaccinations at issue, there were no complaints of respiratory illness or hearing loss. See id. at 32-34. On October 22, 2016, at 58 years old, Petitioner received the flu vaccine and Prevnar 13 vaccine in his left deltoid. Pet. Ex. 2 at 1.

On March 2, 2017, Petitioner presented to his PCP at Redlands Community Hospital and saw Nurse Lo. Pet. Ex. 3 at 38. Petitioner complained of fatigue and requested his testosterone be checked. Id. Petitioner also reported that “since having flu shot[,] [he] had upper respiratory symptoms of cough, cold[,] [] congestion[,] and wheezing.” Id. It was noted that Petitioner “continue[d] to smoke daily.” Id. Physical examination showed bilateral bulging of the tympanic membranes, fluid behind the tympanic membranes, and erythema. Id. The assessment was URI and bilateral effusion.<sup>17</sup> Id. at 39. Petitioner was prescribed antibiotics and an inhaler. Id. Blood work drawn on March 3, 2017 revealed his hemoglobin A1c (“HbA1c”)<sup>18</sup> was high at 9.3 (normal range 4.8-5.6). Id. at 42.

Petitioner returned to Nurse Lo on March 15, 2017. Pet. Ex. 3 at 44. He complained of “continue[d] . . . persistent fatigue” and attributed it to low testosterone levels. Id. His testosterone was low at 335 (normal range 348-1197 ng/dL). Id. at 42. Due to his recently elevated HbA1c of 9.3, Petitioner’s diabetes medication was changed to Invokana 100 mg, one tab per day. Id. at 44. Petitioner was also educated on continuing his metformin and Lantus insulin for his diabetes. Id.

On March 29, Petitioner called his PCP’s office complaining of “bilateral hearing loss” and “persistent hearing changes.” Pet. Ex. 3 at 37. Petitioner requested a referral to an ENT specialist. Id. An ENT referral was submitted. Id.

On April 12, 2017, Petitioner presented to ENT specialist, Dr. Roy. Pet. Ex. 4 at 1. History indicated that Petitioner “developed the flu and a severe URI in December and ever since then[,] [Petitioner] had bilateral ear pain and hearing loss.”<sup>19</sup> [Petitioner] took [antibiotics] and got a little better and then last week he developed worsening symptoms along with constant

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<sup>17</sup> Effusion is “the escape of fluid into a part or tissue.” Effusion, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=15649> (last visited Nov. 17, 2023).

<sup>18</sup> HbA1c is a type of glycated hemoglobin; “its levels are increased in persons with poorly controlled diabetes mellitus.” Hemoglobin A<sub>1c</sub>, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=80470> (last visited Dec. 5, 2023).

<sup>19</sup> This appears to be the first report by Petitioner of the history of his hearing loss and he relates the onset to “severe URI in December.” Pet. Ex. 4 at 1.



tinnitus in both ears.” Id. The family history included “Hearing Loss: Brother \* Meniere’s Disease.” Id. Review of symptoms noted hearing loss, ringing in ears, and ear pain, as well as difficulty breathing, postnasal drip, snoring, sore throat, and cough. Id. at 2. Physical examination revealed the right tympanic membrane was clear and intact “but retracted with fluid in the middle ear.” Id. The left tympanic membrane was “clear and severely scarred, with fluid in the middle ear.” Id. Both external auditory canals (“EAC”) were clear. Id. Dr. Roy diagnosed Petitioner with bilateral chronic mucoid otitis media,<sup>20</sup> bilateral tinnitus, and bilateral unspecified hearing loss. Id. Dr. Roy wrote that Petitioner had “bilateral mucoid otitis media after the flu.” Id. at 3. He prescribed Petitioner antibiotics (Levaquin) and steroids (Medrol Dosepak). Id.

A hearing evaluation was conducted on April 14, 2017. Pet. Ex. 5 at 1; Pet. Ex. 13 at 1. There is no interpretation of this evaluation in the medical records.<sup>21</sup> An audiogram was performed on April 24, 2017. Pet. Ex. 4 at 4. The audiogram was interpreted by Dr. Roy as showing “bilateral, mild to moderate, predominantly conductive hearing loss across all frequencies.” Id. at 6. Dr. Roy’s interpretation did not mention SNHL. See id. Dr. Roy’s assessment was bilateral “chronic mucoid otitis media,” “tinnitus,” and “conductive hearing loss.” Id. at 6.

At the visit on April 24, Petitioner reported that he took antibiotics and steroids, but his symptoms had not improved. Pet. Ex. 4 at 5. Examination again revealed that the right tympanic membrane was clear and intact “but retracted with fluid in the middle ear,” and the left tympanic membrane was “clear and severely scarred, with fluid in the middle ear.” Id. at 6. Dr. Roy wrote that Petitioner had “chronic tinnitus and conductive hearing loss after developing an

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<sup>20</sup> Otitis media is “inflammation of the middle ear.” Otitis Media, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=95455> (last visited Nov. 17, 2023). Mucoid (resembling mucus) otitis media is “serious otitis media in which the secretion is particularly viscous.” Otitis Media, Mucoid, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=95459> (last visited Nov. 17, 2023); Mucoid, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=32378> (last visited Nov. 17, 2023). Serous otitis media is “chronic otitis media marked by serous effusion into the middle ear.” Otitis Media, Serous, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=95462> (last visited Nov. 17, 2023).

<sup>21</sup> The records are somewhat confusing in that audiograms from 2017 and 2019 are contained in the same exhibits, so care must be taken to determine the date of testing.

illness after a flu and [Pevnar 13] vaccine.” Id. He recommended bilateral tympanostomy tubes.<sup>22</sup> Id.

On April 27, 2017, Petitioner underwent bilateral myringotomy with tube placement. Pet. Ex. 4 at 9. History indicated Petitioner’s “ear symptoms [had] not changed since his last visit.” Id. at 8. The procedure confirmed “[t]hick mucoid fluid was in [his] middle ear space bilat[erally], which was removed with suction.” Id. at 9. The assessment remained bilateral chronic mucoid otitis media and bilateral conductive hearing loss. Id.

Petitioner followed up with his PCP on May 10, 2017. Pet. Ex. 3 at 48. History indicated that Petitioner had tubes placed bilaterally in his ears but that he “continue[d] to have tinnitus.” Id. Petitioner reported that an audiogram was done and that he was “diagnosed with bilateral conductive hearing loss.” Id. He also reported that he was “currently in an open case due to side effects of vaccines from flu shot” and requested lab results for antibodies. Id. Nurse Lo ordered labs for immunoglobulin (“Ig”) A, IgM, IgG, pneumococcal antibodies, and mumps antibodies to assess “[p]otential side effect of vaccination.”<sup>23</sup> Id. at 49. The labs obtained on May 12 showed that 23 serotypes of pneumococcal antibody were tested (including a number of serotypes not included in Pevnar 13 vaccine). Id. at 51-52. Antibodies for seven stereotyped were low, but the other 15 were in the normal reference range. Id. at 51-52. IgA, IgM, and IgG were all within the normal reference range. Id. at 53. Mumps IgG was positive, indicating past exposure to the virus or vaccination. Id. at 54. HbA1c was high at 8.7 (normal range 4.8-5.6). Id. at 53.

On June 6, 2017, Petitioner returned to Dr. Roy and reported that his hearing was “slowly getting better.” Pet. Ex. 4 at 11. “He ha[d] no pain or drainage from the ears, but [did] have intermittent popping and crackling sounds.” Id. Dr. Roy listed bilateral conductive hearing loss as one of Petitioner’s current problems. Id. It was also noted that a sleep study performed on May 14, 2017 determined he had sleep apnea. Id. at 10-11. Examination revealed the tubes in

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<sup>22</sup> A tympanostomy tube is “a tube inserted after myringotomy in chronic cases of middle ear effusion, such as in secretory or mucoid otitis media; it provides ventilation and drainage for the middle ear during healing.” Ventilation Tube, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=115337> (last visited Nov. 17, 2023). Myringotomy, also called tympanostomy, is “the creation of a hole in the tympanic membrane.” Myringotomy, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=32972> (last visited Nov. 17, 2023).

<sup>23</sup> It does not appear that tests were done for antibodies against inner ear antigens. For description of inner ear antigens, see Pet. Ex. 18-9 at 2-3.



his ears were in place and dry. Id. at 13. A nasopharyngoscopy revealed collapsed oropharyngeal airway and sluggish mobility of the right cords.<sup>24</sup> Id.

From September 2017 to August 2018, Petitioner saw his PCP for treatment of his other medical conditions such as diabetes myelitis, coronary artery disease, allergic rhinitis, and postnasal drip. See Pet. Ex. 3 at 68-69, 74-75, 77-78, 87-88, 91-92; Pet. Ex. 15 at 4. Petitioner did not mention issues with his hearing at these appointments. See Pet. Ex. 3 at 68-69, 74-75, 77-78, 87-88, 91-92; Pet. Ex. 15 at 4.

On November 27, 2018, Petitioner saw Anita Adorador, NP, at his PCP office for a follow-up. Pet. Ex 16 at 2. Nurse Adorador noted hearing loss and “[p]er [Petitioner], [it was] secondary to flu vaccine given several years ago.” Id. at 3. Petitioner requested a referral to ENT. Id.

An audiogram was conducted on March 26, 2019 at Miracle Ear, and the handwritten note on the study stated “mild to moderate sensory neural deafness[,] moderate for high frequency (sensory neural)[,] [n]o conductive hearing loss.” Pet. Ex. 5 at 3. It appears only the right ear was tested on this date. See id. Another audiogram performed on April 9, again at Miracle Ear, remarked “[r]ight ear mild to moderate sensorineural loss. Left ear severe sensorineural loss.” Id. at 4.

Throughout 2021, Petitioner presented to Progressive Neurology & Sleep Medicine Associates for his sleep apnea and a stroke he had in September 2020. See Pet. Ex. 20 at 3-32. On October 5, 2021, Petitioner had a follow-up there with neurologist Dr. LeAnn Hoang. Pet. Ex. 20 at 17. Dr. Hoang documented that Petitioner asked

if MRI/[magnetic resonance angiography (“MRA”)]<sup>[25]</sup> identified a cause for [SNHL]. [Petitioner] [r]eport[ed] he had a recent audiogram this year that showed mild-moderate [right] [SNHL] and moderate-severe [left] [SNHL]. [Petitioner] [r]eport[ed] he had hearing loss that started after [flu] and [Prevnar 13] vaccine in 2016. It was initially thought to be conductive, as there were air fluid levels behind ear drums, but that was removed and he had some improvement, but then progressive bilateral hearing loss restarted. He [] filed a lawsuit regarding his [SNHL], which he attribute[d] to the vaccine.

Id. Dr. Hoang’s impression was that Petitioner’s hearing loss was not due to a vascular problem. Id. at 18. Dr. Hoang wrote a letter that same day stating that Petitioner’s brain MRI and head

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<sup>24</sup> Petitioner was assessed with paralysis of vocal cords and larynx. Pet. Ex. 4 at 13. Given the upper airway obstruction, vocal fold motion impairment, and sleep apnea, a magnetic resonance imaging (“MRI”) and computed tomography (“CT”) scan were ordered. Id. at 15. A June 19, 2017 chest CT scan noted a few pulmonary micronodules that were most likely post-infectious/inflammatory. Pet. Ex. 3 at 64-65.

<sup>25</sup> The MRI and MRA were done on October 8, 2020. Pet. Ex. 19 at 27-28. It appears this imaging was done in relation to Petitioner’s stroke, not for his hearing loss. See id.

MRA from October 2020 were reviewed and that “clinical history and neuroimaging do not support a vascular etiology.” Id. at 33.

On February 11, 2022, Petitioner underwent an audiogram which showed “bilateral mild SNHL rising to normal with bilateral mild high frequency SNHL.” Pet. Ex. 21 at 1. Impression was “mild SNHL.” Id. On February 16, Petitioner was seen by Dr. Johnny Arruda who diagnosed Petitioner with SNHL. Id. at 6. Dr. Arruda’s history indicated Petitioner reported bilateral hearing loss for the past five years, had bilateral tubes placed in 2017, that his last hearing test was in 2019, and that he had a history of chronic ear infections. Id. Dr. Arruda wrote “[t]he issue with infection and hearing loss apparently related to a flu vaccine and [Prevnar 13] vaccine.” Id. Dr. Arruda’s diagnosis was hearing loss and history of acute otitis media. Id. at 8.

No other relevant medical records were filed.

### **3. Affidavit of Petitioner**

On July 24, 2019, Petitioner executed an affidavit. Pet. Ex. 1 at 4. He attended Army Medical College in Islamabad, Pakistan on a full scholarship from the Jordan government. Id. at ¶ 2. Thereafter, he served as a physician in the Jordan Army for 23 years, retiring with the rank of Brigadier General. Id. Upon retirement, he opened a private clinic in Jordan where he practiced medicine until 2015, when he moved to the United States. Id. At that time, his position was Senior Medical Consultant, “the highest attainable by medical doctors in Jordan.” Id. He holds specializations in internal medicine, hematology, and oncology from the Jordan Medical Board. Id. He has also received medical training in the United States; however, Petitioner is not licensed to practice medicine in the United States. Id.; Pet. Ex. 19 at 7, 9. Petitioner’s wife was also a physician in the Jordan Army. Pet. Ex. 1 at ¶ 3. At the time Petitioner executed his affidavit, Petitioner was an instructor with Key Medical Resources where he taught a variety of medical subjects to healthcare professionals and was the primary instructor for nurses seeking specialized certifications. Id.

Prior to the vaccinations at issue, Petitioner recalled not having hearing problems or problems with his ears. Pet. Ex. 1 at ¶ 4. He “never experienced any symptoms of any ear disease such as tinnitus or vertigo and did not experience any other hearing disturbances.” Id.

On October 22, 2016, Petitioner received the flu vaccine and the Prevnar 13 vaccine. Pet. Ex. 1 at ¶ 5. This was the first flu vaccine he had ever received. Id.

Approximately one week later, Petitioner recounted “experiencing symptoms that resembled a[] [URI] and then later started noticing issues with [his] ears and hearing.” Pet. Ex. 1 at ¶ 7. Petitioner prescribed himself a 10-day course of amoxicillin, a three-day course of Zithromax, and an antihistamine. Id. He averred “[t]his would be a typical course of treatment for the symptoms [he] was experiencing.” Id. Over the following weeks, he did not see any improvement. Id. at ¶ 8. Towards the end of December, he prescribed himself a second course of antibiotics, levofloxacin, “a very strong antibiotic.” Id.

By January 2017, Petitioner was still experiencing symptoms. Pet. Ex. 1 at ¶ 9. He did not seek emergent treatment then because in his experience as a physician, “there was not really anything else that [he] believed they would prescribe for [him] other than what [he] had already been taking. All of the steps [Petitioner] followed would have been part of the standard course of treatment for [his] symptoms.” Id. Instead, he called his PCP to schedule an appointment and was interested in seeking a referral to an ENT. Id.

Petitioner saw his PCP on March 2, 2017 “as [his] condition had begun to deteriorate further despite multiple courses of antibiotics.” Pet. Ex. 1 at ¶ 10. He was diagnosed with a URI and bilateral effusion and prescribed more antibiotics. Id. Petitioner returned to his PCP on March 15 for a previously scheduled well visit. Id. at ¶ 11. He stated that “[a]lthough the report from that date mentions [his] continued fatigue, [he] also raised the issue of his continued hearing problems at this appointment as well.” Id. But upon reviewing the report, however, it did “not appear [to Petitioner] that this was noted by [his] physician.” Id. By the end of March, Petitioner’s hearing loss was “increasing in both ears” and he did not see improvement with medications. Id. at ¶ 12. He again called his PCP and requested a formal referral to an ENT. Id.

In April 2017, Petitioner saw Dr. Roy and was diagnosed with otitis media, bilateral tinnitus, and bilateral hearing loss. Pet. Ex. 1 at ¶ 13. Petitioner also recalled Dr. Roy noting a collection of fluid behind his eardrum. Id. at ¶¶ 13-14. A subsequent audiogram showed moderate to severe hearing impairments. Id. Dr. Roy prescribed antibiotics and steroids but again, Petitioner saw no improvement. Id. at ¶ 13.

Petitioner ultimately underwent a bilateral tympanostomy, a surgery recommended by Dr. Roy in which “tubes were placed to remove fluid from the middle ear.” Pet. Ex. 1 at ¶ 17. After the surgery, Petitioner averred that his “condition improved somewhat and while [he] was able to hear better than before the surgery, some residual hearing loss remained.” Id. at ¶ 19. Petitioner opined that in April 2019, an audiogram confirmed he has SNHL “with severe to profound impairments in [his] left ear and mild to moderate hearing loss in [his] right ear.” Id. at ¶ 20.

Finally, Petitioner concluded that as a physician, he knew that “in certain rare cases[,] vaccinations may disturb the immune system in a way that can result in serious medical problems. Such problems may be transient or permanent.” Pet. Ex. 1 at ¶ 21. Thus, Petitioner “believe[d] that [he] suffered severe transient immune deficiency in reacting to the flu shot. As [his] immune system could not fight off the [URI], [he] suffered significant symptoms and the vaccination interacted with the [URI] to create an enhanced adverse reaction resulting in [his] hearing loss.” Id.

#### **4. Email from Dr. Mansour Karadsheh**

After receiving the May 12, 2017 lab results, Petitioner sent them to Dr. Karadsheh, “an immunologist that [he] kn[ew] from his native country of Jordan, for a consultation.”<sup>26</sup> Pet. Ex.

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<sup>26</sup> The correspondence sent to Dr. Karadsheh from Petitioner was not filed.

1 at ¶ 15. Dr. Karadsheh is a consultant physician in allergy and immunology.<sup>27</sup> Pet. Ex. 6 at 1. On July 7, 2017, Dr. Karadsheh emailed “Dr. Hatter” stating,

[i]t is known that the simultaneous administration of [flu] and [Prevnam 13] vaccine may induce a state of immunodeficiency<sup>[28]</sup> in a previously healthy subject[.]. In [Petitioner’s] case, the infection was severe enough to cause the complications of native diseases, that [his] immune system could not control. This is shown by the normal immunoglobulins, with poor response to the antigens in the vaccine constituents.

Id. Petitioner averred that Dr. Karadsheh reviewed the results and emailed him back “verifying his belief that the administration of the vaccinations caused [Petitioner] to develop an immunodeficiency which prevented [his] body from fighting off the [URI].” Pet. Ex. 1 at ¶ 15.

### 5. Declaration of Dr. Deborshi Roy

Dr. Roy was Petitioner’s treating ENT physician in 2017.<sup>29</sup> Pet. Ex. 7 at 2. In June 2018, he executed a declaration. Id. Dr. Roy is a licensed and board-certified otolaryngologist. Id. at ¶ 1. At the time of his declaration, he practiced at the ENT & Sinus Center in California and stated that on April 12, 2017, Petitioner “presented to [him] with complaints of bilateral ear pain, tinnitus, and hearing loss.” Id. at ¶ 2.

Dr. Roy recalled Petitioner reporting that “he started developing [] symptomology after receiving a[] [flu] vaccination and [Prevnam 13] vaccination several months previously.” Pet. Ex. 7 at ¶ 3. Dr. Roy wrote that Petitioner “stated that he started developing symptoms consistent with a[] [URI] and he indicated that he prescribed himself two rounds of antibiotics over the

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<sup>27</sup> Petitioner did not file a curriculum vitae or other evidence of Dr. Karadsheh’s education, medical training, or licensure. The information about his specialty is based on the copy of the emailed that was filed. Pet. Ex. 6 at 1.

<sup>28</sup> Immunodeficiency is “a deficiency of immune response or a disorder characterized by deficient immune response; classified as antibody (B cell), cellular (T cell), or combined immunodeficiency, or phagocytic dysfunction disorders.” Immunodeficiency, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=24872> (last visited Dec. 21, 2023). It is a “failure in humoral antibody or cell-mediated limbs of the immune response. If attributable to intrinsic defects in T and/or B lymphocytes, the condition is termed primary []. If the defect results from loss of antibody and/or lymphocytes, the condition is secondary [.]” Immunodeficiency, Illustrated Dictionary of Immunology 362 (Julius M. Cruse & Robert E. Lewis eds., 3d ed. 2009). That is, it “can be primary (due to a defect in the immune mechanism itself) or secondary (dependent on another disease process).” Immunodeficiency, Stedman’s Medical Dictionary 952 (28th ed. 2006).

<sup>29</sup> The medical records filed by Petitioner show that he saw Dr. Roy from April 12, 2017 until June 6, 2017. See Pet. Ex. 4. Based on the medical records filed, it does not appear Petitioner has seen Dr. Roy since June 6, 2017.

ensuing months.” Id. at ¶ 4. After Petitioner’s condition did not improve, he came under Dr. Roy’s care. Id. at ¶ 5. Dr. Roy placed him on antibiotics and steroids, but when audiogram and examination indicated Petitioner’s symptoms did not improve on the medications, he recommended and performed a bilateral tympanostomy tube placement procedure on April 27, 2017. Id.

Dr. Roy opined, to a reasonable degree of medical certainty, that the vaccines Petitioner received “were a substantial factor in causing an immune deficiency that resulted in the upper respiratory symptoms and consequential bilateral ear pain, tinnitus, otitis media, and hearing loss and that these conditions necessitated [his] treatment and the resulting surgery.” Pet. Ex. 7 at ¶ 6. Dr. Roy’s declaration did not reference SNHL or AIED.

#### **D. Medical Literature Submitted with Petition**

Along with the petition, Petitioner filed medical literature to support his claim. Pet. Exs. 8-12. This literature was not discussed by Petitioner’s expert.

The first piece of medical literature was from the Institute of Medicine (“IOM”)<sup>30</sup> which acknowledged a “biologic plausibility that mumps vaccine could cause sensorineural deafness” and, to a lesser extent, that the measles vaccine “could cause sensorineural deafness.” Pet. Ex. 8 at 31. However, they concluded “[t]he evidence [was] inadequate to accept or reject a causal relation between measles or mumps vaccines and sensorineural deafness.” Id. Moreover, Petitioner did not receive the measles or mumps vaccines.

The second was a case report of a 33-year-old man who developed hearing loss within 24 hours of receiving the meningococcal and tetanus-diphtheria vaccines. Pet. Ex. 9 at 1.<sup>31</sup> Functional recovery was achieved after about six months. Id. at 4. Despite investigations excluding possible related pathologies, the cause of the patient’s hearing loss remained unknown. Id. Accordingly, the authors wrote that a “post-vaccinal correlation seem[ed] possible.” Id. at 3. “The short period of time between the vaccinations and the onset of the hearing loss suggest[ed] . . . that it may be the result of an adverse reaction to vaccines.” Id. at 4.

The third was a case report of an 11-year-old with sudden hearing loss after receiving a rabies immunization two days prior. Pet. Ex. 10 at 1.<sup>32</sup> The authors noted that side effects after immunization can include sudden hearing loss, “although this is rarely observed.” Id.

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<sup>30</sup> Inst. of Med., Measles and Mumps Vaccines, in Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 118 (Kathleen Stratton et al. eds., 1994). The IOM is now the National Academy of Medicine.

<sup>31</sup> Federica De Marco et al., Post Vaccinal Temporary Sensorineural Hearing Loss, 15 Int’l J. Env’t Rsch. & Pub. Health 1780 (2018)

<sup>32</sup> Oğuz Güçlü & Fevzi Sefa Dereköy, Sudden Hearing Loss After Rabies Vaccination, 30 Balkan Med. J. 327 (2013).

The fourth piece of medical literature filed discussed nine reports of children with SNHL after measles, mumps, and rubella (“MMR”) vaccinations. Pet. Ex. 11 at 1.<sup>33</sup> In three cases, the deafness was found to be unrelated to the MMR vaccine. Id. In six cases, the cause was unknown, but MMR remained a possible etiology. Id. The authors concluded “[a]ny risk of deafness after MMR [immunization] is small and must be weighed against the risks of the natural diseases.” Id. at 2.

Lastly, Petitioner filed a document that purports to show there have been approximately 280 Vaccine Adverse Event Reporting System (“VAERS”) reports filed alleging the development of hearing loss after vaccination. See Pet. Ex. 12; Pet. Br. at 19, ¶ 81. There is no identification on this document about where the information came from, who obtained it, or what it applies to.

## **E. Expert Reports**

### **1. Petitioner’s Expert, Dr. Richard A. Beck<sup>34</sup>**

#### **a. Background and Qualifications**

Dr. Beck is a practicing, board-certified otolaryngologist-head and neck surgeon. Pet. Ex. 18 at 1. He received his M.D. at the University of Miami in Florida, and completed an otolaryngology-head and neck surgery residency at Madigan Army Medical Center. Id.; Pet. Ex. 18-1 at 1. Dr. Beck served in the United States Army for nine years during which he was Chief of otolaryngology-head and neck surgery at Eisenhower Army Medical Center. Pet. Ex. 18 at 1. Dr. Beck has been in private practice since his honorable discharge in 1993. Id. In his practice, he routinely evaluates, diagnoses, and treats individuals with ear problems including AIED, SNHL, and tinnitus. Id.

#### **b. Diagnosis Opinion**

Dr. Beck opined that Petitioner has AIED. Pet. Ex. 18 at 10; see also Pet. Ex. 19 at 7. Specifically, he opined “the fluctuating nature and bilateral sudden [SNHL] following the administration of [the Prevnar 13 and flu] vaccinations . . . are responsible for [AIED].” Pet. Ex. 18 at 6-7; see also Pet. Ex. 19 at 4. But see Pet. Ex. 19 at 15, ¶ 17 (opining Petitioner “experienced AIED which caused bilateral asymmetric sudden [SNHL]”). According to Dr. Beck, Petitioner’s AIED “manifested in the SNHL which [was] asymmetric and [] fluctuated since onset.” Pet. Ex. 18 at 10.

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<sup>33</sup> Barbara J.A. Stewart & P. Umesh Prabhu, Reports of Sensorineural Deafness After Measles, Mumps, and Rubella Immunisation, 69 Archives Disease Childhood 153 (1993).

<sup>34</sup> Petitioner filed two expert reports from Dr. Beck. Pet. Exs. 18-19.



Citing medical literature, he posited the “[d]iagnosis of AIED is accepted when the clinical condition manifests progressive bilateral, fluctuating, [SNHL] over a period of weeks to months.” Pet. Ex. 18 at 11 (citing Pet. Ex. 18-7 at 1 (“AIED hearing loss is usually rapid, bilateral, and progressive . . . .”); Pet. Ex. 18-8 at 1 (“[P]atient[s] usually present[] with bilateral, asymmetric, progressive hearing loss over a course of days to months.”);<sup>35</sup> Pet. Ex. 18-9 at 1 (“The clinical expression of AIED is a progressive bilateral and not always symmetric SNHL, progressively developing between [three] and 90 days, which typically benefits from a steroid and immunosuppressive therapy.”); Pet. Ex. 18-10 at 1 (“The hallmark of this clinically diagnosed condition is the presence of a rapidly progressive, often fluctuating, bilateral [SNHL] over a period of weeks to months.”)).<sup>36</sup> Dr. Beck did not specifically discuss any of this medical literature.

As applied to Petitioner, Dr. Beck posited the “fluctuating nature and bilateral asymmetric sudden [SNHL] defines [AIED] which [] resulted in bilateral asymmetric sudden [SNHL] of a severe to profound degree in [Petitioner’s] left ear and a moderate to severe degree in [Petitioner’s] right ear as documented by audiometric testing in April 2019.” Pet. Ex. 19 at 7. Dr. Beck did not further interpret any of Petitioner’s audiograms. Dr. Beck averred that Petitioner’s SNHL “on audiometric testing has shown fluctuance and asymmetry on serial examination as expected for AIED which is progressive<sup>[37]</sup> and further impairment is expected.” Id. at 22.

One of the references cited by Dr. Beck stated that because “there are no standardized diagnostic criteria or reliable diagnostic tests for the diagnosis of AIED,” the diagnosis of “immune-mediated cochleovestibular disorders” is based on clinical symptoms, lab tests (“demonstrating the presence in the serum of antibodies or activated T cells against inner ear antigens”), and on the response to immunosuppressive treatment. Pet. Ex. 18-9 at 1, 3 (“[O]nly a small percentage of patients (14%) is steroids responsive.”); see also Pet. Ex. 18-10 at 6 (“[N]ot

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<sup>35</sup> Andrew J. Griffith, Biological and Clinical Aspects of Autoimmune Inner Ear Disease, 65 Yale J. Biology & Med. 17 (1992).

<sup>36</sup> R. Bovo et al., Immune-Mediated Inner Ear Disease, 126 Acta Oto-Laryngologica 1012 (2006).

<sup>37</sup> In addition to Dr. Beck characterizing Petitioner’s hearing loss as progressive, he also characterized it as sudden. Dr. Beck opined the medical records, Petitioner’s affidavit, and a phone call with Petitioner on December 3, 2021 indicated that prior to vaccination, Petitioner did not have hearing problems or any issues with his ears and “clearly document[ed] the sudden bilateral onset of otologic symptoms within one week postvaccination.” Pet. Ex. 19 at 18.

all patients respond to [steroid therapy in the same manner . . .”). The authors recommended that serologic tests<sup>38</sup> be conducted in all patients with suspected AIED. Id. at 3.

Similarly, Sakano and Harris suggested “the presence of additional systemic autoimmune findings, diagnosis of autoimmune disorder,<sup>[39]</sup> or laboratory findings of autoimmune markers may aid in the diagnosis.” Pet. Ex. 19-5 at 1; see also Pet. Ex. 18-4 at 16 (suggesting evidence of an association between autoimmune disease and sudden SNHL); Pet. Ex. 18-6 at 3 (finding that sudden SNHL is sometimes associated with systematic immune-mediated diseases and that patients can have “evidence of T-cell and antibody recognition of inner ear antigens”).<sup>40</sup>

Dr. Beck did not discuss the lack of systemic autoimmune findings or inflammatory markers as suggested by the medical literature. See Pet. Ex. 18-9 at 3, 4 tbl.2; Pet. Ex. 19-5 at 1. He did not address the fact that Petitioner never underwent testing suggested by Ciorba et al. or that Petitioner was not diagnosed with AIED. Dr. Beck did not respond to Respondent’s expert’s (Dr. Bigelow) position that Petitioner does not meet the diagnostic criteria for AIED or that Petitioner did not have sudden bilateral asymmetric SNHL.

### **c. Causation Opinion**

#### **i. Althen Prong One**

Dr. Beck opined the Prevnar 13 and flu vaccinations administered on October 22, 2016 are responsible for causing Petitioner’s AIED. Pet. Ex. 19 at 7. Dr. Beck’s proposed theory is

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<sup>38</sup> Some of the tests recommended by Ciorba et al. include erythrocyte sedimentation rate (“ESR”), C-reactive protein, antinuclear antibody (“ANA”), antineutrophil cytoplasmic antibody (“ANCA”), and human leukocyte antigen (“HLA”). Pet. Ex. 18-9 at 4 tbl.2.

<sup>39</sup> An autoimmune disorder is “a disorder caused by an immune response directed against self antigens. The usual characteristics are demonstrable circulating autoantibodies or cell-mediated immunity against autoantigens, inflammatory lesions caused by immunologically competent cells or immune complexes in tissues containing the autoantigens, and clinical or experimental evidence that the autoimmune process is pathogenic and not secondary to other tissue damage.” Autoimmune Disease, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=70076> (last visited Dec. 7, 2023). They include “diseases such as systemic lupus erythematosus and rheumatoid arthritis in which cells of the adaptive immune system such as autoreactive T and B cells become overreactive and produce self-reactive T-cell and antibody responses.” Barton F. Haynes et al., The Immune System in Health and Disease, in 2 Harrison’s Principles of Internal Medicine 2671 (Joseph Loscalzo et al. eds., 21st ed. 2022).

<sup>40</sup> Benjamin E. Schreiber et al., Sudden Sensorineural Hearing Loss, 375 Lancet 1203 (2010).

that “[i]mmune-mediated mechanisms activate the innate immune system<sup>[41]</sup> within the inner ear and thereby produce antigens<sup>[42]</sup> which are known to cause damage to the cochleovestibular structures.” Pet. Ex. 18 at 11. Dr. Beck did not explain this theory further.

Notably, Dr. Beck conceded that it is not known what triggers the autoimmune response in the pathophysiology of AIED. Pet. Ex. 19 at 15 (citing Pet. Ex. 19-5 at 2). But he stated “[t]here are some studies that suggest that autoantibodies are produced against inner ear protein through molecular mimicry in response to viral or bacterial infection.” *Id.* (quoting Pet. Ex. 19-5 at 2). Dr. Beck did not discuss molecular mimicry any further. And he did not explain how this statement about viral and bacterial infection related to his opinion that the flu and Prevnar 13 vaccines could cause AIED. But Dr. Beck did opine that URIs are typically viral and do “not result in immune-mediated mechanisms activating the innate immune system within the inner ear, thereby producing antigens which are known to cause damage to the cochleovestibular structures.” Pet. Ex. 18 at 13 (emphasis omitted).

## 1. Medical Literature

Dr. Beck cited medical literature, but he did not discuss any of it in his expert reports to support his opinions.<sup>43</sup> Nonetheless, the literature referenced by Dr. Beck was helpful in understanding what is or what is not known about the cause of AIED.

Ciorba et al. acknowledged that “the pathogenetic mechanisms of AIED remain unclear.” Pet. Ex. 18-9 at 1, 5 (“The inflammatory and the immune-mediated pathogenetic mechanisms are still not completely known . . .”). The authors suggested a number of different mechanisms including, “(1) deposition of circulating immune complexes . . . ; (2) vestibule-cochlear autoantibodies . . . ; (3) vasculitis; (4) micro-thrombosis[;] and (5) electrochemical alterations.” *Id.* at 2-3. “Many antigens in the inner ear and possibly the endolymphatic sac have been recognized as possible AIED targets.” *Id.* at 2. The authors explained that activation of the

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<sup>41</sup> The innate immune system is an “ancient immune recognition system of host cells bearing germline-encoded pattern receptors [] that recognize pathogens and trigger a variety of mechanisms of pathogen elimination.” Haynes et al., *supra* note 39, at 2671. In contrast, the adaptive immune system is a “recently evolved system of immune responses mediated by T and B lymphocytes. Immune responses by these cells are based on specific antigen recognition . . . .” *Id.* The adaptive immune system is “characterized by antigen-specific responses to a foreign antigen or pathogen.” *Id.* at 2689. “[F]ollowing the initial contact with antigen . . . , subsequent antigen exposure leads to more rapid and vigorous immune responses (immunologic memory).” *Id.*

<sup>42</sup> An antigen is “any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response, that is, with specific antibody or specifically sensitized T lymphocytes, or both.” *Antigen*, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=3334> (last visited Dec. 22, 2023).

<sup>43</sup> In his second report, Dr. Beck does discuss medical literature cited by Respondent’s experts; however, it is not supportive of his proposed causal mechanism.

immune system involves “the release of interleukin (IL)-1 $\beta$ ,” and that “immunoglobulins can target, by chemotaxis, the inner ear in response to antigenic stimuli.” Id. In summary, Ciorba et al. summarized a number of leading theories, but did not reach a conclusion about the mechanism of pathogenesis.

Similarly, Sakano and Harris did not identify the pathogenesis of AIED. Pet. Ex. 19-5 at 2. They noted that studies suggest “antibody concentration within the inner ear,” but they did not identify any probable mechanism. Id. They concluded that “[w]hatever the initial insult or trigger may be, the autoimmune process leads to destructive changes in the inner ear and ultimately neural degeneration and hearing loss.” Id. at 6.

Mijovic et al. explained that the “strongest pathogenic evidence is that of an immune-mediated disease. The inner ear . . . may mount an immune response against foreign and self-antigens damaging sensory structures within it.” Pet. Ex. 18-11 at 2. “Both humoral and cell-mediated mechanisms are involved in the autoimmune injury to the inner ear.” Id. “Cochlear innate immunity has been proposed to contribute to the initiation of a local adaptive immune response following antigen challenge.” Id. “[A]s a consequence of a yet identified trigger (i.e. antibody cross-reactivity, viral injury, trauma, vascular insult, surgical damage and others) damaging the inner ear, lymphocytes from the systemic circulation are exposed to proteins of the cochlea.” Id. Thus, the authors concluded the trigger is not yet identified. See id.

Schreiber et al. wrote that sudden SNHL is sometimes associated with systematic immune-mediated diseases and that patients can have “evidence of T-cell and antibody recognition of inner ear antigens. However, the role of tissue-specific immune-responses is poorly defined.” Pet. Ex. 18-6 at 3.

Huang et al.<sup>44</sup> is a case report of a 17-year-old girl who developed bilateral sudden deafness (moderate SNHL) 14 hours after receiving an H1N1 vaccination. Pet. Ex. 18-2 at 1. The authors stated that “acute loss of cochlear function” following vaccination is a rare event and thought to be associated with an antigen-antibody reaction. Id. at 1-2. They discussed hearing loss following other vaccines, including live virus vaccines, where the “causative factors of deafness were considered to be the viral components of the vaccines . . . or the latent autoimmune response to the vaccine contents.” Id. at 2. But the authors acknowledged “the mechanism of bilateral sudden hearing loss induced by H1N1 vaccine is unknown.” Id.

Chen et al.<sup>45</sup> discussed three potential mechanisms proposed to explain how a viral infection can cause sudden SNHL. Pet. Ex. 18-3 at 2. However, the authors concluded that while studies show viral infection is one etiology of sudden SNHL, “there is little research proving or clearly indicating the pathogenesis of this disease” and “further research is needed.” Id. at 5.

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<sup>44</sup> Hsueh-Hsin Huang et al., Bilateral Sudden Deafness Following H1N1 Vaccination, 143 *Otolaryngology Head & Neck Surgery* 849 (2010).

<sup>45</sup> Xin Chen et al., Role of Viral Infection in Sudden Hearing Loss, 47 *J. Int’l Med. Rsch.* 2865 (2019).

Regarding diagnostic testing, Dr. Beck averred that “[d]iagnostic testing, including serologic assessment, immunologic testing, and medical imaging, is limited in proving the etiology” of sudden SNHL. Pet. Ex. 18 at 11. For example, Chen et al. discussed limitations to studies. Pet. Ex. 18-3 at 5. The authors wrote that “an indirect diagnosis [of sudden hearing loss] can often be obtained by detecting class antibodies to identify primary infection, which is most frequently responsible for overt disease. However, pathology can be induced by an endogenous reinfection that, in most cases, would not give rise to IgM.” *Id.* “This in turn can lead to underestimation in the role of viruses as etiological agents in sudden hearing loss.” *Id.* Nonetheless, Dr. Beck opined that “histopathologic studies . . . indicate the changes commonly found are consistent with viral infection and immunologic injury.” Pet. Ex. 18 at 11 (citing Pet. Ex. 18-5 at 4 (finding “[t]he parallel incidence of [idiopathic sudden hearing loss] and positive viral seroconversion suggests that the two are closely related and that viral infection is a major cause of idiopathic sudden hearing loss]”)). *But see* Pet. Ex. 18-6 at 2 (concluding that while “many viruses have been postulated as possible causes of sudden [SNHL], [] serological, epidemiological, and histopathological data are not conclusive”).

Dr. Beck averred that none of the medical literature cited by Respondent’s experts is applicable here because it was not about the “dual simultaneous vaccination” of Prevnar 13 and flu. Pet. Ex. 19 at 11. However, Dr. Beck discussed an article relied on by Dr. Bigelow that analyzed the concomitant administration of vaccines. *Id.* at 21 (citing Resp. Ex. C, Tab 4).<sup>46</sup> Dr. Beck quoted Frenck et al. for the proposition that “[m]ore systemic adverse events were seen with the concomitant administration of [Prevnar 13] and [trivalent inactivated flu vaccine] than with the single administration of either vaccine.” *Id.* (quoting Resp. Ex. C, Tab 4 at 7). Notably, Dr. Beck left out the remainder of the paragraph which states that “[g]iven that the two vaccines were administered concomitantly, the higher rate of systemic events does not appear to be unusual and is not considered clinically meaningful.” Resp. Ex. C, Tab 4 at 7. Moreover, this specific part of the article was discussing local site reactions, not URI, otitis media, or SNHL. *Id.* at 6 tbl.7, 7.

## ii. Althen Prong Two

Dr. Beck then veered from his immune-mediated mechanism and adopted a theory based on “immunodeficiency.” Pet. Ex. 18 at 11-12. He wrote that Petitioner’s “simultaneous administration of [flu] and [Prevnar 13] vaccines [were] the reason for inducing a state of immunodeficiency.” *Id.* at 12. However, Dr. Beck did not explain the definition of immunodeficiency or how it caused AIED. He also did not explain how the administration of vaccines causes immunodeficiency.

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<sup>46</sup> Robert W. Frenck et al., Randomized, Controlled Trial of a 13-Valent Pneumococcal Conjugate Vaccine Administered Concomitantly with an Influenza Vaccine in Healthy Adults, 19 Clinical & Vaccine Immunology 1296 (2012). This is also cited as Pet. Ex. 19-14.

According to Dr. Beck, the testing done on Petitioner on May 12, 2017 “showed an abnormal immune response.”<sup>47</sup> Pet. Ex. 18 at 9. Petitioner’s results showed that seven serotypes of pneumococcal antibodies were low, but the other 15 were in the normal reference range. Pet. Ex. 3 at 51-52. IgA, IgM, and IgG were normal. Id. Dr. Beck opined the results “indicated a marked abnormal immune system response as multiple pneumococcal antibody subtypes were abnormally low despite the previous administration of Prevnar 13 vaccination on [October 22, 2016].” Pet. Ex. 18 at 6. Dr. Beck averred “[o]bjective laboratory data clearly demonstrate[] [Petitioner’s] abnormal immunologic responses as he showed low antibody titers to many strains of pneumococcus including several which were included in the Prevnar 13 vaccine.” Id. at 9, 12 (“The pneumococcal antibody results were markedly abnormal with low antibody titers to numerous serotypes of *Streptococcus pneumoniae* [“*S. pneumoniae*”]), including several of the serotypes included in the Prevnar 13 vaccine.”).

Dr. Beck conceded that “to assess an individual’s response to vaccination requires comparison” to baseline testing and “there are no prevaccination serologic test results for comparison.” Pet. Ex. 19 at 10. Regardless, he maintained that “there is no data in the medical record to disprove the abnormal immunologic response which [Petitioner] demonstrated in test results following the administration of Prevnar 13 and [flu] vaccinations on [October 22, 2016].” Id. Dr. Beck did not explain or provide any references to support his opinion that the test results represent an immunodeficiency or an abnormal immune response to vaccination or how it could lead to AIED.

Dr. Beck quoted Dr. Karadsheh who wrote “[i]t is known that the simultaneous administration of [flu] and [Prevnar 13] vaccine may induce a state of immunodeficiency in a previously health subject[].” Pet. Ex. 18 at 6 (quoting Pet. Ex. 6 at 1).

He also relied on Dr. Roy’s declaration where he opined the vaccinations “were a substantial factor in causing an immune deficiency that resulted in upper respiratory symptoms and consequential bilateral ear pain, tinnitus, otitis media, and hearing loss.” Pet. Ex. 18 at 9 (quoting Pet. Ex. 7 at ¶ 6). Dr. Beck believed this was consistent with his own opinion that Petitioner had “an abnormal immune-mediated response which [] result[ed] in damage from

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<sup>47</sup> Dr. Beck appeared to use “abnormal immune response” and “immunodeficiency” interchangeably. See, e.g., Pet. Ex. 18 at 10 (opining Petitioner had an “abnormal immunologic response following the administration of Prevnar 13 and [flu] vaccinations on [October 22, 2016], [that] resulted in the development of [AIED]”), 12 (opining Petitioner’s “simultaneous administration of [flu] and [Prevnar 13] vaccines [were] the reason for inducing a state of immunodeficiency”).



[AIED].” Pet. Ex. 19 at 19 (emphasis omitted).<sup>48</sup> He did not explain how the vaccines caused Petitioner’s upper respiratory symptoms, or how that would have led to AIED.

As for alternative causes, Dr. Beck opined that “[b]ecause the incidence of bilateral sudden hearing loss is rare[,] the possibility of [] neoplastic, age-related [], or idiopathic cause is extremely improbable.” Pet. Ex. 18 at 11. Furthermore, he averred that Petitioner’s other medical conditions “would not produce asymmetric [SNHL] as in the case for [Petitioner], and thus are not medically reasonable alternative explanations.” *Id.* at 13 (emphasis omitted).

As discussed in more detail above under prong one, Dr. Beck opined it would be “highly improbable for a simple/uncomplicated URI . . . to result in sudden [SNHL] bilaterally.” Pet. Ex. 18 at 13.

Regarding Petitioner’s history of diabetes and coronary artery disease, Dr. Beck also opined that it would be “highly improbable” for diabetes or vascular disease “to result in sudden [SNHL] bilaterally.” Pet. Ex. 18 at 13. He noted Petitioner “had diabetes mellitus for years and alleged cardiovascular disease for years without any incidence or complaints of hearing loss or ear problems. It was only after receiving the vaccinations . . . that [Petitioner] suddenly experienced [] otologic symptoms.” Pet. Ex. 19 at 12.

Moreover, Dr. Beck posited that Petitioner’s treating physicians “did not consider diabetes mellitus as a risk factor for hearing loss”<sup>49</sup> nor did they “request audiometric testing be performed, even with the known medical history of diabetes.” Pet. Ex. 19 at 13. Dr. Beck opined “[t]hese practices [were] in keeping with American Diabetes association [] clinical guidelines recommendations” because “a hearing evaluation is not included in the advocated end-organ assessment” for diabetics. *Id.* (quoting Pet. Ex. 19-1 at 2).<sup>50</sup> However, as Dr. Beck recognized, Baiduc and Helzner wrote that persons with diabetes also suffer from SNHL and that “hearing loss is a possible consequence of [diabetes mellitus].” *Id.* (quoting Pet. Ex. 19-1 at 2).

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<sup>48</sup> Because Dr. Beck opined that URIs do “not result in immune-mediated mechanisms activating the innate immune system within the inner ear, thereby producing antigens which are known to cause damage to the cochleovestibular structures,” it appears Dr. Beck did not believe the URI was a contributing factor to the cause of Petitioner’s hearing loss. Pet. Ex. 18 at 13 (emphasis omitted). Thus, this statement seems inconsistent with Dr. Beck’s reliance on Dr. Roy’s statement that Petitioner’s vaccines “were a substantial factor in causing an immune deficiency that resulted in the upper respiratory symptoms and consequential . . . hearing loss.” Pet. Ex. 7 at ¶ 6.

<sup>49</sup> Dr. Beck also quoted Dr. Hoang who, after reviewing Petitioner’s MRI and MRA, wrote that Petitioner’s “clinical history and neuroimaging do not support a vascular etiology as the cause for his [SNHL].” Pet. Ex. 19 at 20.

<sup>50</sup> Rachel R. Baiduc & Elizabeth P. Helzner, Epidemiology of Diabetes and Hearing Loss, 40 *Seminars Hearings* 281 (2019). This is also cited as Resp. Ex. A, Tab 1.

Whether Petitioner's diabetes was controlled, an issue raised by Respondent's experts, Dr. Beck averred that there is an "ongoing debate about the 'optimal' HbA1c" level and that "glycemic targets must be individualized." Pet. Ex. 19 at 14 (quoting Pet. Ex. 19-3 at 1).<sup>51</sup> Klein and Buse discussed the various results of trials analyzing microvascular risk and HbA1c levels. Pet. Ex. 19-3 at 5. Current guidelines "recommend that individualized HbA1c targets be established based on the patient's age, life expectancy, comorbidities[,] and risk of hypoglycaemia." Id. According to Dr. Beck's phone interview with Petitioner on December 3, 2021, "[Petitioner's] current endocrinologist has achieved improvement in diabetes control by implementing this approach." Pet. Ex. 19 at 14. Klein and Buse summarized, based on current guidelines and trials, that the "overarching goal" should be an HbA1c less than or equal to 7.5. Pet. Ex. 19-3 at 11. Petitioner's HbA1c level prior to vaccination was elevated at 8.4. Pet. Ex. 3 at 32. Petitioner's HbA1c level after vaccination continued to be high at 9.3 (March 3, 2017) and 8.7 (May 12, 2017). Id. at 42, 53.

Dr. Beck opined that medical literature regarding diabetes and hearing loss cited by Respondent's expert, Dr. Whitton, does not apply because Petitioner had sudden SNHL,<sup>52</sup> whereas Srinivas et al.<sup>53</sup> stated that hearing loss in patients with diabetes mellitus is "usually gradually progressive." Pet. Ex. 19 at 14 (citing Pet. Ex. 19-4 at 1). Further, he quoted the authors for the proposition that "[t]he pathophysiology of diabetes related hearing loss is speculative." Id. (quoting Pet. Ex. 19-4 at 1).

### iii. Althen Prong Three

Dr. Beck opined "the abnormal immune-mediated response that [Petitioner] experienced affected both ears one week postvaccination." Pet. Ex. 19 at 19. He averred "[t]he clinical manifestation of bilateral [SNHL] caused by uncontrolled immune system response is progressive and often asymmetric, developing between [three] and 90 days." Pet. Ex. 18 at 12 (citing Pet. Exs. 18-4, 18-7, 18-9). Dr. Beck relied on Petitioner's affidavit for the basis for his opinion that onset was one week after vaccination. Id.

Dr. Beck posited that patients with sudden SNHL often delay seeking medical attention and that Petitioner instead instituted "self-directed interventions." Pet. Ex. 18 at 8; see also Pet. Ex. 18-6 at 1. "[W]ithin one [] week following the combined vaccinations[,] [Petitioner] began

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<sup>51</sup> Klara R. Klein & John B. Buse, The Trials and Tribulations of Determining HbA<sub>1c</sub> Targets for Diabetes Mellitus, 16 Nature Revs. Endocrinology 717 (2020). This is also cited as Resp. Ex. A, Tab 3.

<sup>52</sup> Again, the undersigned notes that Dr. Beck classified Petitioner's SNHL as sudden as evidenced here, and as progressive as discussed in the diagnosis section above.

<sup>53</sup> C.V. Srinivas et al., Clinical Study to Evaluate the Association Between Sensorineural Hearing Loss and Diabetes Mellitus in Poorly Controlled Patients Whose HbA<sub>1c</sub> >8, 68 Indian J. Otolaryngology Head & Neck Surgery 191 (2016). This is also cited as Resp. Ex. A, Tab 4.

to experience what resembled a[] [URI] and bilateral ear (otologic) symptoms including changes of his hearing in both ears.” Pet. Ex. 19 at 6. Dr. Beck opined “[t]his sudden onset of ear (otologic) symptoms meets the definition of sudden [SNHL] although [Petitioner] did not recognize the severity of the problem and did not seek immediate medical attention.” Id.

Dr. Beck criticized Dr. Whitton’s use of calculating the incidence rate of SNHL to support the temporal association as coincidental because the literature he referenced, Black et al.<sup>54</sup> and Alexander and Harris,<sup>55</sup> “fails to meet his own . . . requirements.”<sup>56</sup> Pet. Ex. 19 at 17 (citing Resp. Ex. A, Tabs 9-10). Dr. Beck opined “the data used by [Dr.] Whitton to ‘calculate the incidence of SNHL’ which estimates ‘unilateral loss of hearing’ is not applicable and results in an erroneous conclusion which does not apply to [Petitioner’s] bilateral asymmetric sudden [SNHL].” Id. (emphasis omitted).

In summary, Dr. Beck opined the “proximate temporal relationship of onset of symptoms considering the etiology of [AIED] occurring as it does in this case within days to months[,] it is medically acceptable to infer causation-in-fact.” Pet. Ex. 18 at 13.

## **2. Respondent’s Expert, Dr. Douglas C. Bigelow<sup>57</sup>**

### **a. Background and Qualifications**

Dr. Bigelow is board certified in otolaryngology head and neck surgery, with a subspecialty of neurotology.<sup>58</sup> Resp. Ex. C at 2. He received his M.D. from the University of Minnesota School of Medicine, and completed an otolaryngology-head and neck surgery

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<sup>54</sup> Steven Black et al., Importance of Background Rates of Disease in Assessment of Vaccine Safety During Mass Immunisation with Pandemic H1N1 Influenza Vaccines, 374 Pub. Health 2115 (2009). This is also cited as Pet. Ex. 19-9.

<sup>55</sup> Thomas H. Alexander & Jeffrey P. Harris, Incidence of Sudden Sensorineural Hearing Loss, 34 Otolaryngology & Neurotology 1586 (2013). This is also cited as Pet. Ex. 19-10.

<sup>56</sup> Dr. Whitton relied on Black et al. for calculating the frequency in which a disease will occur after vaccination. Resp. Ex. A at 10-11. The authors warned about the uncertainty in the estimates when considering rare events and miscoding of events. Resp. Ex. A, Tab 9 at 6-7. Dr. Whitton relied on Alexander and Harris to obtain data regarding the incidence of SNHL. Resp. Ex. A at 10-11. Dr. Beck stated that Alexander and Harris incorrectly described sudden SNHL as unilateral hearing loss. Pet. Ex. 19 at 17 (citing Resp. Ex. A, Tab 10 at 1). Importantly, the data collected was derived from the coding for this diagnosis. Id. (citing Resp. Ex. A, Tab 10 at 2).

<sup>57</sup> Respondent filed two expert reports from Dr. Bigelow. Resp. Exs. C, F.

<sup>58</sup> Neurotology is the “neurological study of the ear.” Neurotology, Merriam-Webster Dictionary Online, <https://www.merriam-webster.com/medical/neuro-otology> (last visited Jan. 2, 2024).

residency at Washington University, St. Louis. Resp. Ex. D at 1. He is currently an Associate Professor in the Department of Otorhinolaryngology: Head and Neck Surgery at the University of Pennsylvania School of Medicine. Id. He is also the Director of the Division of Otology/Neurotology at the University of Pennsylvania Medical Center in Philadelphia. Id. at 2. Dr. Bigelow has “over thirty years of experience as an attending physician managing patients with otology problems, hearing loss, sudden hearing loss, chronic otitis, otitis media with effusion, dizziness, tinnitus, vestibular migraine, acoustic neuromas etc. in a university tertiary care setting.” Resp. Ex. C at 2.

## **b. Diagnosis Opinion**

Dr. Bigelow disagreed that Petitioner’s diagnosis is AIED. Resp. Ex. F at 3, 8. He explained that “AIED is a bilateral condition that usually begins with sudden SNHL in one ear with involvement of the other ear usually within days to weeks after onset.” Id. at 3. He also acknowledged the definition and criteria described by Ciorba et al., discussed above. Id. at 2-3; see also Resp. Ex. C at 13-14. He noted several characteristics were inconsistent with a diagnosis of AIED—primarily that Petitioner’s initial hearing loss was mainly conductive, not sudden, and the subsequent SNHL likely developed progressively. Resp. Ex. F at 2-4; Resp. Ex. C at 13. He analyzed Petitioner’s audiograms to explain his reasons.

## **i. 2017 Audiograms**

First, Dr. Bigelow opined that “the vast majority of Petitioner’s hearing loss, when he was first evaluated, was conductive<sup>[59]</sup> and was due to [otitis media with effusion].” Resp. Ex. F at 3-4; see also Resp. Ex. C at 14. He opined that Petitioner’s 2017 audiograms “demonstrated a predominately conductive hearing loss that would be consistent with the mucoid fluid in the middle ear.” Resp. Ex. C at 11. Specifically, he noted that the audiogram from Dr. Roy’s office, on April 24, 2017, “demonstrated a bilateral symmetric mostly conductive hearing loss due to the fluid present in [Petitioner’s] middle ear.” Id. at 12 (citing Pet. Ex. 4 at 4); see also Resp. Ex. F at 3 (“[U]pon reviewing the audiogram, it is clear that the vast majority of the hearing loss present at that time was a conductive hearing loss [], not a [SNHL].”).

Dr. Bigelow explained “[f]luid in the middle ear, also known as otitis media with effusion [] causes a conductive hearing loss, fullness/pressure in the ear and commonly tinnitus.” Resp. Ex. C at 12 (citing Resp. Ex. C, Tab 1).<sup>60</sup> It is “a condition in which there is fluid in the middle

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<sup>59</sup> The April 24, 2017 audiogram was interpreted by Dr. Roy as showing “bilateral, mild to moderate, predominately conductive hearing loss.” Pet. Ex. 4 at 6. Diagnosis was “chronic mucoid otitis media, bilateral, tinnitus, bilateral, and conductive hearing loss, bilateral.” Id.

<sup>60</sup> Fredrick T. Searight et al., Otitis Media with Effusion, StatPearls [Internet], <https://www.ncbi.nlm.nih.gov/books/NBK538293/> (last updated Aug. 11, 2021). This is also cited as Pet. Ex. 19-11.

ear, but no signs of acute infection.” Resp. Ex. C, Tab 1 at 2. “As fluid builds up in the middle ear and [e]ustachian tube, it places pressure on the tympanic membrane. The pressure prevents the tympanic membrane from vibrating properly, decreases sound conduction, and therefore results in a decrease in patient hearing.” Id.

Otitis media with effusion is usually due to eustachian tube dysfunction and is often associated with a URI.<sup>61</sup> Resp. Ex. C at 12 (citing Resp. Ex. C, Tab 1 at 3; Resp. Ex. C, Tab 2).<sup>62</sup> Dr. Bigelow averred nasal pathology can contribute to eustachian tube dysfunction. Id. Additionally, “[s]moking has been shown to be associated with reduced ciliary beat frequency in samples of middle-ear mucosa taken from adults with [otitis media with effusion].” Resp. Ex. C, Tab 2 at 3. Dr. Bigelow averred that “AIED does not cause conductive hearing loss or [otitis media with effusion],” and Dr. Bigelow’s research did not “state[] or infer[] that vaccinations are the cause of [otitis media with effusion].” Resp. Ex. F at 3, 6-7.

Dr. Bigelow opined that Petitioner’s “multiple underlying conditions,” “persistent URI symptoms,” and smoking habits, “especially when they are all occurring together,” could contribute to eustachian tube dysfunction and otitis media with effusion. Resp. Ex. C at 12; see also Resp. Ex. F at 6. He noted Petitioner “was a smoker and continued to smoke while he had the URI symptoms.” Resp. Ex. C at 12. The chest CT scan from June 19, 2017 “identified diffuse bronchial wall thickening suggestive of smoking related bronchitis, which would suggest reactive airway disease from smoking.” Id. Moreover, he pointed out that “Dr. Roy identified a deviated septum and enlarged turbinates in the nose as well as obstructive sleep apnea, oropharyngeal airway narrowing due to redundant tissue and a complete collapse of the oropharyngeal airway” on June 6, 2017. Id. (citing Pet. Ex. 4 at 10-15).

Next, Dr. Bigelow explained that in 2017, while Petitioner’s primary diagnosis was conductive hearing loss, Petitioner also had some symmetrical, normal to mild SNHL. Resp. Ex. C at 11; Resp. Ex. F at 3. However, Dr. Bigelow attributed this to Petitioner’s age and medical history. Resp. Ex. C at 11; Resp. Ex. F at 3. He opined “[t]he measurement of [P]etitioner’s sensorineural reserve (inner ear function) revealed symmetric sensorineural hearing that was in the normal to mild hearing loss range in both ears with thresholds that were between 10 dB and 40 dB (normal is considered to be from 20 to 25 dB and less).” Resp. Ex. F at 3. Dr. Bigelow opined the minimal amount of SNHL demonstrated in the audiograms “is often seen in someone of [Petitioner’s] age, with a family history of hearing loss and multiple medical and vascular conditions.” Resp. Ex. C at 11; see also Resp. Ex. F at 3.

Moreover, Dr. Bigelow opined the records do not show that Petitioner “experienced a bilateral sudden hearing loss.” Resp. Ex. C at 11. “The first notation in the medical record of

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<sup>61</sup> Otitis media with effusion is also often unilateral. Resp. Ex. C, Tab 1 at 3.

<sup>62</sup> R. Mills & I. Hathorn, Aetiology and Pathology of Otitis Media with Effusion in Adult Life, 130 J. Laryngology & Otology 418 (2016). This is also cited as Pet. Ex. 19-12.

hearing loss was on [March 29, 2017] when [Nurse] Lo recorded that “[Petitioner] called, report[ed] bilateral hearing loss with persistent hearing changes.” Id. (quoting Pet. Ex. 3 at 37). Petitioner stated that “the URI symptoms began approximately [one] week after the vaccination and ‘then [he] later started noticing issues with [his] ears and hearing.’” Id. (quoting Pet. Ex. 1 at ¶ 7). Dr. Bigelow noted that Dr. Roy’s records from April 12, 2017 report that “[Petitioner] developed the flu and a severe URI in December and ever since then he’s had bilateral ear pain and hearing loss. He took a Z-pack and got a little better and then last week developed worsening symptoms along with constant tinnitus in both ears.” Id. (quoting Pet. Ex. 4 at 1). Dr. Bigelow opined that “[d]epending on when in December the symptoms began[,] this would be between [six] and 10 weeks after the vaccinations,” which is “well past the [three] to 90 day time period after vaccinations that the Ciorba [et al.] article describes.” Id. at 11, 14; see also Resp. Ex. F at 3.

In summary, Dr. Bigelow opined the 2017 audiograms showed predominantly conductive hearing loss and not SNHL characteristic of AIED. Further, if the vaccinations had caused AIED he posited there would have been a sudden, asymmetric bilateral SNHL “readily apparent” on the April 14 and April 24, 2017 audiograms. Resp. Ex. F at 3. However, neither of those audiograms showed “asymmetric or significant SNHL.” Id.

## ii. 2019 Audiograms

Dr. Bigelow noted that Petitioner’s conductive hearing loss improved after the placement of ventilation tubes. Resp. Ex. F at 3. This is evidenced by the March 26, 2019 and April 9, 2019 audiograms which did not show any conductive hearing loss. Id. (citing Pet. Ex. 5 at 3-4).

The March 26, 2019 audiogram was only of the right ear. Resp. Ex. C at 13 (citing Pet. Ex. 5 at 3). Dr. Bigelow opined it demonstrated improvement from 2017 as there was no conductive hearing loss, and that the sensorineural hearing level in Petitioner’s right ear was unchanged compared to the 2017 audiograms. Resp. Ex. F at 3; Resp. Ex. C at 13 (opining the sensorineural reserve from the March 26, 2019 audiogram “was the same (within 5 dB, which is test-retest variability) to improved when compared to the April 2017 hearing test”). Dr. Bigelow opined this does not support a diagnosis of AIED because Petitioner’s right-sided hearing was “unchanged, not fluctuating or progressive, so there [was] not bilateral involvement which is a key component of AIED.” Resp. Ex. F at 3; see also Resp. Ex. C at 13 (“The fact that the right ear was unchanged since 2017 would [] not corroborate Dr. Beck’s statement that the hearing loss was fluctuating.”).

On April 9, 2019, an audiogram was performed on both ears. Resp. Ex. C at 13 (citing Pet. Ex. 5 at 4). Dr. Bigelow opined the right ear was unchanged, and the left ear “demonstrated a moderately severe to severe [SNHL] across all frequencies with no residual conductive hearing loss.” Id. Although the 2019 audiogram showed the “[SNHL] in the left ear was significantly worse when compared to the April 24, 2017 audiogram,” Dr. Bigelow opined “it is not known



when that worsening occurred since there were no audiograms provided between April 2017 and March 2019 or after April 2019 to determine how his hearing [] changed overtime.” Id.

Based on the evidence, Dr. Bigelow opined it was “likely the hearing loss on the left was a progressive loss over time as neither the medical records nor [Petitioner’s] affidavit suggest there was a sudden loss of hearing after the April 2017 evaluations.” Resp. Ex. C at 13. “If there was a sudden loss of hearing on the left, [Dr. Bigelow] would have expected [Petitioner] to have contacted his medical providers.” Id. He added that because “a progressive loss occurs slowly over time, most patients will not notice the change until significant hearing loss has occurred which may be why [Petitioner] did not obtain another audiogram for [two] years after his April 2017 test.” Id.

In summary, Dr. Bigelow opined that Petitioner did not have symptoms consistent with AIED. Resp. Ex. C at 15; Resp. Ex. F at 2. Specifically, Petitioner “did not have bilateral fluctuating sensorineural hearing loss as neither the medical records, audiograms nor [Petitioner’s] affidavit document or suggest a fluctuating hearing loss or sudden SNHL.” Resp. Ex. C at 15; see also Resp. Ex. F at 4. Therefore, he concluded Petitioner “would not meet the criteria to diagnose AIED.” Resp. Ex. C at 14, 16.

### **c. Causation Opinion**

#### **i. Althen Prong One**

In response to Petitioner’s theory based on immunodeficiency, Dr. Bigelow opined that “[i]f there is a reduced immune response, then that would make it less likely that an adverse event would occur. You would be more likely to experience an immune mediated adverse event if there was a hyperactive immune response, not a reduced immune response.” Resp. Ex. F at 7.

Regarding immunodeficiency following vaccination, Dr. Bigelow cited the Centers for Disease Control and Prevention (“CDC”)<sup>63</sup> which stated that “studies demonstrate concomitant administration of [Prevnam 13 vaccine] and [trivalent inactivated flu vaccine] is immunogenic and safe.” Resp. Ex. C at 15 (quoting Resp. Ex. C, Tab 5 at 3).

Frenck et al. conducted a randomized double-blind study to evaluate the immunogenicity and tolerability of a Prevnam 13 vaccine co-administered with the trivalent flu vaccination. Resp. Ex. C, Tab 4 at 1. “Immunogenicity results show[ed] that immune responses for [trivalent inactivated flu vaccine] antigens after the concomitant administration of [Prevnam 13] and [trivalent inactivated flu vaccine] to healthy adults aged 50 to 59 years [were] robust and noninferior to immune responses after [trivalent inactivated flu vaccine] given separately.” Id. at 7. “[A]ntipneumococcal IgG responses were lower for all serotypes and statistically significantly lower for [eight] of 13 serotypes after concomitant administration of [Prevnam 13]

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<sup>63</sup> Administering Pneumococcal Vaccines, Ctrs. for Disease Control & Prevention, <https://www.cdc.gov/vaccines/vpd/pneumo/hcp/administering-vaccine.html> (last reviewed Nov. 21, 2019). This is also cited as Pet. Ex. 19-15.

and [trivalent inactivated flu vaccine] compared with administration of [Prevnam 13] alone.” Id. However, the authors posited “it is likely that [Prevnam 13] establishes immunologic memory, a common characteristic of conjugated polysaccharide vaccines that is not seen with purified polysaccharide vaccines.” Id. Thus, “[o]verall, the concomitant administration of [Prevnam 13] and [trivalent inactivated flu vaccine] was demonstrated to be immunogenic and well tolerated.” Id.

Dr. Bigelow cited Baxter et al.,<sup>64</sup> which analyzed the association between vaccinations and sudden SNHL. Resp. Ex. C, Tab 6 at 1. Baxter et al. indicated that “[i]n all risk intervals prior to the onset of [sudden SNHL], [the authors] found no evidence of increased risk of immunization compared with matched controls.” Resp. Ex. C at 17 (quoting Resp. Ex. C, Tab 6 at 1). “Review of the 13 VAERS reports of [sudden SNHL] following [trivalent inactivated flu vaccine] seemed to indicate the possibility of clustering in time of [sudden SNHL] with respect to the [trivalent inactivated flu vaccine] vaccination; however, temporal association does not prove causation when assessing the association of vaccine adverse events.” Id. (quoting Resp. Ex. A, Tab 8 at 3). Dr. Bigelow opined “[t]his is a very powerful study with a massive data base that specifically looked at and did not find an association with vaccination and sudden SNHL.” Resp. Ex. F at 5.

Moreover, Dr. Bigelow noted that while Dr. Beck quoted Dr. Karadsheh who stated “[i]t is known that the simultaneous administration of [flu] and pneumococcal vaccine may induce a state of immunodeficiency in a previously healthy subject[],” Dr. Karadsheh “[did] not provide any studies to back up his statement and opinion.” Resp. Ex. C at 15 (first quoting Pet. Ex. 18 at 9; and then quoting Pet. Ex. 6 at 1).

## **ii. Althen Prong Two**

### **1. No Abnormal Immune Response**

Dr. Bigelow opined there is no evidence of an abnormal immune response. Regarding Petitioner’s laboratory results, Dr. Bigelow noted all but two of the serotypes in Prevnam 13 were in the normal range. Resp. Ex. C at 15. He opined “[t]his would not confirm a significantly abnormal response.” Id.

Dr. Bigelow disagreed with Dr. Roy “that the vaccine caused immunodeficiency that resulted in the URI, ear pain, tinnitus, otitis media, and hearing loss.” Resp. Ex. C at 15. He averred that even Dr. Beck contradicted this statement by opining that a URI would not result in

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<sup>64</sup> Roger Baxter et al., Sudden-Onset Sensorineural Hearing Loss After Immunization: A Case-Centered Analysis, 155 Otolaryngology Head & Neck Surgery 81 (2016). This is also cited as Resp. Ex. A, Tab 8; Pet. Ex. 19-8.

AIED.<sup>65</sup> Id.; see also Pet. Ex. 18 at 13. Dr. Bigelow agreed with Dr. Beck “that the URI [Petitioner] had in late 2016 and 2017 did not cause any immune related ear problems or hearing loss.” Resp. Ex. C at 15.

## 2. Progression of Hearing Loss

Dr. Bigelow opined Petitioner developed “bilateral [otitis media with effusion] which caused a significant conductive hearing loss that was initially diagnosed in March 2017, objectively measured with an audiogram in April 2017 and definitively treated with bilateral ventilation tube placement in April 2017.” Resp. Ex. C at 14.

The first notation of hearing loss in the medical records was on March 29, 2017, more than five months after the vaccinations. Resp. Ex. C at 9, 11 (citing Pet. Ex. 3 at 37). Petitioner had audiograms done in April 2017 which Dr. Bigelow opined showed “predominately conductive hearing loss that would be consistent with the mucoid fluid in the middle ear with a sensorineural reserve (inner ear function) that was in the normal to mild hearing loss range bilaterally.” Res. Ex. C at 11. Petitioner’s conductive hearing loss improved after the placement of ventilation tubes on April 27, 2017. Id. at 13; Resp. Ex. F at 3; Pet. Ex. 4 at 9. The next audiogram was not until March 2019 and showed no conductive hearing loss and Petitioner’s right-sided SNHL was the same as in 2017. Resp. Ex. C at 13; Resp. Ex. F at 3; Pet. Ex. 5 at 3. Another audiogram in April 2019 showed “a moderately severe to severe [SNHL] across all frequencies [in the left ear] with no residual conductive hearing loss” in either ear. Resp. Ex. C at 13 (citing Pet. Ex. 5 at 3).

Dr. Bigelow opined Petitioner’s otitis media with effusion caused his conductive hearing loss shown in the 2017 audiograms, but “it did not cause his asymmetric SNHL” as shown on the April 9, 2019 audiogram. Resp. Ex. F at 6. He also stated that the vaccinations did not cause the otitis media with effusion. Id. at 7.

He averred the “etiology of [Petitioner’s] left sided asymmetric SNHL is not known.” Resp. Ex. C at 14. But “in the majority of cases of sudden or progressive SNHL, a specific cause is never identified.” Id. According to Dr. Bigelow, Petitioner’s “left sided SNHL that occurred after the April 2017 audiogram was most likely progressive, but if there was a sudden left sided SNHL that occurred after April 2017, it would have occurred somewhere between [six] months and [two-and-one-half] years after the vaccinations and would not have had any association or relationship to the vaccinations.” Resp. Ex. F at 6.

Dr. Bigelow added that “[a]nyone with a unilateral hearing loss needs to have an MRI scan that adequately covers the internal auditory canals and cerebellopontine angles to rule out any lesions such as an acoustic neuroma that can cause unilateral hearing loss.” Resp. Ex. C at 14. If contrast is not utilized then, at a minimum, “high resolution T2 images through the

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<sup>65</sup> Dr. Beck opined URIs are typically viral and do “not result in immune-mediated mechanisms activating the innate immune system within the inner ear, thereby producing antigens which are known to cause damage to the cochleovestibular structures.” Pet. Ex. 18 at 13 (emphasis omitted).

internal auditory canals” would be necessary. Id. “If a lesion was identified on the MRI scan that would certainly account for the asymmetric SNHL.” Id. (citing Resp. Ex. C, Tab 3).<sup>66</sup>

Upon reviewing Petitioner’s MRI, Dr. Bigelow noted that it was “done to evaluate symptoms of ataxia, not asymmetric SNHL, so it was done without contrast.” Resp. Ex. F at 3. He said it was “good that the radiologist noted that the seventh and eighth nerve bundles were normal,” however, “[w]ithout contrast, small lesions that could cause SNHL can sometimes be missed, especially if the scan was not tailored to evaluate the internal auditory canals as would typically be done if it was obtained to evaluate for causes of asymmetric SNHL.” Id. at 3-5. “Thus, while [P]etitioner’s non-contrast MRI would certainly rule out any larger lesions, it may not capture smaller lesions capable of causing [P]etitioner’s asymmetric SNHL.” Id. at 5.

### **3. Alternate Causes/Other Conditions**

Next, Dr. Bigelow reasoned that Petitioner had multiple chronic medical issues “which would have made him more susceptible for chronic airway disease and [eustachian tube dysfunction] and contribute to [otitis media with effusion].” Resp. Ex. C at 15. “However, once the mucoid fluid was removed and the ventilation tubes were placed, the conductive hearing loss resolved completely and did not cause any long-term or permanent problems or hearing loss.” Id. Again, he added that “[t]he [otitis media with effusion] would not cause [Petitioner’s] SNHL.” Id.

One of the chronic illnesses raised by Dr. Bigelow was diabetes. See Resp. Ex. F at 6. He stated that diabetes is a “well-known risk factor for SNHL.” Id. Dr. Bigelow emphasized that “Petitioner had a medical history significant for coronary artery disease with [five] stents, as well as peripheral arterial disease with bilateral femoral stents and hypertension in addition to his diabetes mellitus on insulin and oral medications.” Id. According to him, “these factors place [P]etitioner at a much higher risk for developing SNHL.” Id.

#### **iii. Althen Prong Three**

Dr. Bigelow found Dr. Beck’s opinion—that onset of Petitioner’s AIED symptoms began within days to months following vaccination—to be unsubstantiated by the evidence. Resp. Ex. C at 16.

He noted that Petitioner’s affidavit indicated “that his URI symptoms started approximately [one] week following the vaccinations and that the ear symptoms and hearing loss started sometime later.” Resp. Ex. C at 16. Dr. Bigelow stated that Dr. Roy’s medical records suggest that Petitioner’s “ear symptoms and hearing loss began sometime in December

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<sup>66</sup> Samantha M. Baird et al., Inner Ear and Retrocochlear Pathology on Magnetic Resonance Imaging for Sudden and Progressive Asymmetrical Sensorineural Hearing Loss, 89 ANZ J. Surgery 738 (2019). This is also cited as Pet. Ex. 19-13.

2016<sup>67</sup> which would be somewhere between [six] and 10 weeks after the vaccination.” Id. In March 2017 Petitioner was diagnosed with bilateral middle ear effusion and the “audiograms obtained in April 2017, [six] months after the vaccinations, demonstrated a predominantly conductive hearing loss due to the fluid in the middle ear.” Id.

As stated above, Dr. Bigelow opined “[t]he etiology for the deterioration of the left-sided hearing is unknown, but it occurred sometime after the April 2017 audiograms, which were obtained [six] months after the vaccinations. This would be well outside the window of any [effect] from the October 2016 vaccinations.” Resp. Ex. F at 3, 6; see also Resp. Ex. C at 16 (“Given that the deterioration of the left sided SNHL occurred between [one] and [three] years after the vaccinations there is no temporal relationship between the vaccinations and the SNHL.”).

### **3. Respondent’s Expert, Dr. J. Lindsay Whitton<sup>68</sup>**

#### **a. Background and Qualifications**

Dr. Whitton received his B.Sc. in molecular biology, his M.B., Ch.B. in medicine, and his Ph.D. in herpesvirus transcription from the University of Glasgow in Scotland. Resp. Ex. A at 1. He also completed internships in medicine and surgery and has held various professor positions since 1986. Id.; Resp. Ex. B at 1. At the time Dr. Whitton authored his reports, he was a professor in the Department of Immunology and Microbiology at the Scripps Research Institute in California, where he was previously involved in research. Resp. Ex. A at 1-3; Resp. Ex. B at 1. Dr. Whitton is a member of various professional societies and editorial boards and has authored or co-authored almost 200 publications. Resp. Ex. B at 1-15. Dr. Whitton does not provide patient care, diagnose, or treat patients as he is not licensed as a medical doctor. Resp. Ex. A at 3.

#### **b. Diagnosis Opinion**

Dr. Whitton deferred to Dr. Bigelow on the issue of diagnosis. Resp. Ex. A at 3; Resp. Ex. E at 2.<sup>69</sup> However, Dr. Whitton did note that Dr. Beck’s diagnosis of AIED was not reached by Petitioner’s treating physicians. Resp. Ex. E at 2. As a preface to his opinions about causation, Dr. Whitton explained that in order to critique Petitioner’s theory of causation, he

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<sup>67</sup> Dr. Roy’s history notes from April 12, 2017 document that Petitioner “developed the flu and a severe URI in December and ever since then[,] [Petitioner] had bilateral ear pain and hearing loss.” Pet. Ex. 4 at 1.

<sup>68</sup> Respondent filed two expert reports from Dr. Whitton. Resp. Exs. A, E.

<sup>69</sup> Dr. Whitton commented on the difference between the diagnosis as alleged by Dr. Beck and the diagnosis in the petition and by Petitioner’s treating physicians. See Resp. Ex. E at 1-2. Because Dr. Whitton is not qualified to opine on diagnosis, the undersigned will not discuss this part of his expert report.

relied on the diagnosis of AIED. Resp. Ex. A at 3. But he emphasized that by doing so, he did not concede that Petitioner has AIED. Id.

**c. Causation Opinion**

**i. Althen Prong One**

Dr. Whitton first pointed out some contradictions between Petitioner’s allegations and Dr. Beck’s opinions and conclusions as to the proposed mechanism. Resp. Ex. A at 3. Dr. Whitton stated,

the primary allegation, and theory of causation, made in the [p]etition, and in [P]etitioner’s affidavit, is that the vaccines caused an immunodeficiency, which resulted in an infection, which caused tinnitus and hearing loss that was, at first, mainly conductive, but which became sensorineural, with increasing severity; however, Dr. Beck—although accepting the presence of immunodeficiency—argues that the vaccines caused a disease called autoimmune inner ear disease (AIED) thereby causing tinnitus and [SNHL].

Id.

Dr. Whitton understood Dr. Beck’s alleged mechanism of causation to be that the vaccinations caused an immunodeficiency which, led to a URI that “caused [P]etitioner’s hearing loss and tinnitus.” Resp. Ex. A at 6. Dr. Whitton emphasized that it is “not clear” how autoimmune hearing loss fits with the immunodeficiency theory. Id. Moreover, he is “not aware of any credible evidence that these vaccines, individually, or together, are known to cause ‘immunodeficiency.’” Id. at 8; Resp. Ex. E at 3.

In response to Dr. Beck’s assertion that vaccines can cause SNHL and AIED, Dr. Whitton referenced literature to show there is “no causal association between vaccination and SNHL.” Resp. Ex. A at 10 (emphasis omitted).

Like Dr. Bigelow, Dr. Whitton also cited Baxter et al., a study on sudden onset SNHL in “recipients of [more than] 23 million doses of various vaccines, including [more than] 8 million doses of flu vaccine[] and [more than] 650,000 doses of Prevnar 13 vaccine.” Resp. Ex. A at 10 (citing Resp. Ex. C, Tab 6 at 3 tbl.1). They “found no indication of an increased risk of immunization with any vaccine prior to the development of [sudden SNHL].” Resp. Ex. C, Tab 6 at 9. Baxter et al. concluded their “large-scale analysis applying a case-centered method did not detect any association between [sudden SNHL] and previous receipt of [flu] or other vaccines.” Id. at 1.

In response to Dr. Beck who posited that none of the literature reports on the dual simultaneous vaccination with Prevnar 13 and flu vaccination, Dr. Whitton opined the “fact that a hypothesis (in this case, that Prevnar 13 [and] flu vaccine can cause [sudden SNHL]) has not



been disproven does not mean that we can safely assume that it must be true.” Resp. Ex. E at 6 (emphasis omitted).

## ii. Althen Prong Two

Dr. Whitton opined “[t]here is absolutely no evidence” that Petitioner had an “immunodeficiency.” Resp. Ex. A at 9. First, he opined that Petitioner’s bloodwork “most certainly does not show ‘immunodeficiency.’” Id. at 8 (emphasis omitted). He noted Petitioner’s IgG, IgA, and IgM were all within normal limits and his mumps antibodies were consistent with having either a previous mumps infection or a mumps vaccine. Id. at 8.

Regarding the pneumococcal antibodies, Dr. Whitton opined that the pneumococcal antibodies test Petitioner received “evaluates the levels of antibodies against all 23 of the bacterial polysaccharides that are present in Pneumovax 23 [], an *S. pneumoniae* vaccine that [P]etitioner did not receive.” Resp. Ex. A at 8. Instead, Petitioner received Prevnar 13, which contains polysaccharides from the following 13 strains of *S. pneumoniae*: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. Id. Dr. Whitton explained that Pneumovax 23 contains 12 of those 13 bacterial polysaccharides but also additional serotypes not present in Prevnar 13. Id.; see also Resp. Ex. A, Tab 6 (Prevnar 13 package insert). Therefore, Dr. Whitton explained that when evaluating Petitioner’s laboratory studies, one must review the 12 antibodies specific to the 12 polysaccharides contained in Prevnar 13. Resp. Ex. A at 8. The other levels of antibodies are not relevant to the Prevnar 13 vaccination. Id.

He explained the goal of Prevnar 13 vaccination is “to induce protective levels of antibody against all 13 strains.” Resp. Ex. A at 8. However, “it is common for individuals to fail to respond to one or more of the included polysaccharides” but in practice, it does not mean it was ineffective. Id. at 8-9. Instead, the threshold for an adequate vaccine response is an antibody titer great than 1.3 µg/ml for over 70% of the serotypes. Id. at 9 (citing Resp. Ex. A, Tab 7 at 1).<sup>70</sup> Dr. Whitton charted the different strains of *S. pneumoniae*, indicated which are in Prevnar 13, and compared with Petitioner’s results ranked in descending order. Id. “Petitioner had antibody levels well above the 1.3 µg/ml threshold for 10 of the 12 antibodies that are relevant to Prevnar 13.<sup>[71]</sup> This is an 83.3% response, well above both of the thresholds described above.” Id. Thus, Dr. Whitton concluded, “that [P]etitioner mounted [an] appropriate immune responses to the Prevnar 13 vaccine.” Id. (emphasis omitted); see also Resp. Ex. E at 4.

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<sup>70</sup> Thomas M. Daly et al., Multilaboratory Assessment of Threshold Versus Fold-Change Algorithms for Minimizing Analytical Variability in Multiplexed Pneumococcal IgG Measurements, 21 Clinical & Vaccine Immunology 982 (2014). This is also cited as Pet. Ex. 19-7.

<sup>71</sup> The 6A serotype was not tested. See Pet. Ex. 3 at 51-52. Dr. Whitton explained this was because “the assay that was used was designed to test for antibody responses to a different pneumococcal vaccine, Pneumovax 23, [which] lacks the 6A serotype polysaccharide.” Resp. Ex. E at 3-4.

Further, Petitioner's top 10 antibody levels were specific for polysaccharides in Pevnar 13. Resp. Ex. A at 9. The "antibody titers to polysaccharides that are in Pneumovax 23, but are not in Pevnar 13, [were] much lower." Resp. Ex. E at 4 (emphasis omitted). Dr. Whitton opined that "the very low titers of antibodies to the polysaccharides that are present only in Pneumovax 23 serve as internal negative controls, against which the antibody titers to the Pevnar 13 polysaccharides can be compared, thereby providing additional evidence that [P]etitioner mounted an appropriate immune response to Pevnar 13." Id. at 5. In conclusion, Petitioner's blood work relative to pneumococcal antibodies showed that Petitioner had a normal immune response to the Pevnar 13 vaccination and did not show immunodeficiency. Id.

Second, Dr. Whitton noted that the allegations of immunodeficiency in the petition, Petitioner's affidavit, and Dr. Roy's declaration appeared to come from Dr. Karadsheh. Resp. Ex. A at 6-7. Dr. Whitton stated "that the allegation of immunodeficiency comes from a single source[,] Dr. [] Karadsheh," and it was adopted by Petitioner, Dr. Roy, and Dr. Beck. Id. at 8.

Regarding an alternative cause for Petitioner's hearing loss, Dr. Whitton pointed out that Petitioner suffered two ailments prior to vaccination that are relevant: "poorly-controlled diabetes mellitus[] and [] cardiovascular disease, both of which markedly increase the risk of developing SNHL." Resp. Ex. A at 4, 12.

Dr. Whitton explained that "[d]iabetes is a risk factor for developing hearing loss." Resp. Ex. A at 4 (citing Resp. Ex. A, Tab 2 at 1 ("Diabetes can contribute to hearing loss . . . through numerous mechanisms, including microangiopathy, mitochondrial dysfunction, advance glycation end products/inflammation, and glutamate excitotoxicity."));<sup>72</sup> see also Pet. Ex. 19-4 at 2 ("One of the known complications of [diabetes mellitus] is hearing impairment, especially hearing loss . . ."). Baiduc and Helzner discussed the high prevalence of hearing loss in persons with diabetes and examined studies suggesting a higher incidence of hearing loss in persons with diabetes compared to those without diabetes. Pet. Ex. 19-1 at 1. They found the "epidemiological data support[ed] an association between [diabetes mellitus] and hearing loss." Id. at 6. Additionally, studies showed the risk of developing sudden SNHL was significantly higher in diabetic groups compared with nondiabetic groups, including in the 50-64 year age group. Id. at 14; see also Resp. Ex. A, Tab 4 at 1 (discussing the significant association between older age groups with diabetes and SNHL).

Moreover, "in diabetic patients, the prevalence of hearing loss is higher in those with poorly-controlled disease, as reflected by the blood level of HbA1c, a key indicator of blood glucose control in diabetes." Resp. Ex. A at 4 (citing Pet. Ex. 19-3). In Srinivas et al., "30.8% of people with well-controlled disease (HbA1c [less than] 7) had SNHL, but SNHL was present in 85.7% of those with poorly-controlled diabetes (HbA1c [greater than] 8)." Id. (citing Resp. Ex. A, Tab 4). Petitioner had bloodwork done on April 7, 2016, prior to his vaccinations, and his HbA1c level was flagged as "high" at 8.3. Id. (citing Pet. Ex. 3 at 12). The associated notes indicated that "in adults with diabetes, adequate glycemic control would be indicated by a HbA1c level [less than] 7.0." Id. (citing Pet. Ex. 3 at 12). According to Dr. Whitton, Petitioner's

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<sup>72</sup> Christopher Spankovich & Krishna Yerraguntia, Evaluation and Management of Patients with Diabetes and Hearing Loss, 40 Seminars Hearing 308 (2019). This is also cited as Pet. Ex. 19-2.

diabetes was poorly-controlled months prior to the vaccinations at issue. Id. On March 3, 2017, five months post-vaccination, Petitioner's HbA1c was still high at 9.3. Id. (citing Pet. Ex. 3 at 42). Dr. Whitton referenced several other lab results with elevated HbA1c levels showing that "[t]here is little doubt that Petitioner had, and has, [] poorly-controlled diabetes," which increased the risk of hearing loss. Id. at 5.

Additionally, Dr. Whitton opined "Petitioner also has coronary artery disease and, in persons with diabetes, individuals with coronary heart disease are more likely to develop hearing loss than those without heart disease." Resp. Ex. A at 4 (citing Pet. Ex. 19-1 at 7). Baiduc and Helzner stated, "[i]n addition to age, sex, noise exposure, and genetic predisposition, cardiovascular disease and its antecedents may precipitate hearing loss." Pet. Ex. 19-1 at 1.

### iii. Althen Prong Three

Dr. Whitton opined that "coincidental temporal associations are inevitable, and often are quite common." Resp. Ex. A at 10. He explained that the frequency in which a disease will occur after vaccination can be calculated using (1) the annual incidence of the disease, (2) the number of vaccine doses administered annually, and (3) the time interval between the vaccination and disease onset. Id. He cited Black et al. as an example of applying this by "evaluat[ing] the likelihood of coincidental occurrence between flu vaccination and several neurological diseases including [Guillain-Barré Syndrome ("GBS")], and found that, for every 10 million vaccinees, [approximately] 21 cases of GBS would occur within [six] weeks of vaccination, purely by chance." Id. (citing Resp. Ex. A, Tab 9). Thus, Dr. Whitton believed any temporal association between vaccination and Petitioner's hearing loss was coincidental.

## III. DISCUSSION

### A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy his burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, a petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

“Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case.” Flores v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner’s evidence on a requisite element of the [P]etitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

## **B. Factual Issues**

Petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records).

Medical records, specifically contemporaneous medical records, are presumed to be accurate and generally “warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that “medical records are accurate and complete as to all the patient’s physical conditions”); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013). The weight afforded to contemporaneous records is due to the fact that they “contain information supplied to or by

health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” *Id.* To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is “consistent, clear, cogent, and compelling.” Sanchez v. Sec’y of Health & Hum. Servs., No. 11-685V, 2013 WL 1880825, at \*3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec’y of Health & Hum. Servs., No. 90-2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)), *mot. for rev. den’d*, 142 Fed. Cl. 247 (2019), vacated on other grounds & remanded, 809 F. App’x 843 (Fed Cir. 2020).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at \*19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at \*3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at \*3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

### C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Petitioner must show that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege he suffered a Table Injury, he must prove a vaccine he received actually caused his injury. To do so, Petitioner must establish, by preponderant evidence: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278.



The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether Petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The special master must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in Petitioner’s favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in Petitioner’s favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec’y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

#### IV. DIAGNOSIS ANALYSIS

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the Althen analysis. Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). Since “each prong of the Althen test is decided relative to the injury[,]” determining facts relating to the claimed injury can be significant. Id.

In his petition, Petitioner requests compensation for “bilateral ear pain, tinnitus[,] and hearing loss.” Petition at ¶ 3; Pet. Br. at 1-2. In their joint submission, the parties do not dispute that Petitioner has suffered hearing loss, but they dispute the diagnosis of AIED. Petitioner’s expert, Dr. Beck, opines that Petitioner has AIED. Dr. Beck’s opinions are somewhat confusing and sometimes contradictory. Respondent’s expert, Dr. Bigelow, disagrees and opines Petitioner does not meet the criteria for AIED. Based upon a review of all of the evidence, the undersigned finds that Petitioner does not have AIED for the following reasons.

AIED is characterized by a “a progressive bilateral and asymmetric SNHL profile, which typically benefits from a steroid and immunosuppressive therapy.” Pet. Ex. 18-9 at 1. The



illness progresses over a period of three and 90 days. Although there are no standardized diagnostic criteria for AIED, the medical literature consistently reports that AIED is predominantly sensorineural, not conductive, hearing loss. See e.g., Pet. Ex. 18-8 at 7; Pet. Ex. 18-9 at 1; Pet. Ex. 18-10 at 5.

**A. There Is No Diagnosis by Treating Physicians in the Contemporaneous Medical Records**

The first reason that the undersigned finds that Petitioner did not have AIED is that his post-vaccination hearing loss was not diagnosed as SNHL, and thus, it was not consistent with AIED. Moreover, none of Petitioner's treating physicians diagnosed him with AIED.

Petitioner's audiogram on April 24, 2017 was interpreted by Dr. Roy to show "bilateral, mild to moderate, predominantly conductive hearing loss across all frequencies." Pet. Ex. 4 at 6. Dr. Roy did not diagnose SNHL. Further, Dr. Bigelow opined that the 2017 audiograms showed primarily a conductive hearing loss. This opinion is consistent with Dr. Roy's documented contemporaneous diagnosis. Therefore, the earliest in time diagnostic audiogram shows that Petitioner had conductive hearing loss, and he was not diagnosed with SNHL or AIED.

Petitioner did not have another audiogram until 2019, when an April 9, 2019 audiogram showed severe SNHL in the left ear. Dr. Bigelow explains that Petitioner's SNHL in the left ear was "significantly worse" compared to the April 24, 2017 audiogram. Resp. Ex. C at 13. Still, he was not diagnosed with AIED. Since no audiograms were done between April 2017 and April 2019, it is not possible to determine when or how Petitioner's hearing loss changed over that two-year period of time. Thus, Dr. Bigelow agrees Petitioner had SNHL, but not until 2019, more than two years after Petitioner's vaccinations. The undersigned finds that SNHL that presents two years after vaccination is not temporally associated with vaccination. See Section V.B.

**B. There Is a Lack of Findings Consistent with Autoimmune Hearing Loss**

Next, AIED is thought to be autoimmune in nature, and Petitioner did not have characteristics of an autoimmune condition. One indication of an autoimmune cause of hearing loss described by Ciorba et al. is responsiveness to steroid treatment. Petitioner was prescribed systemic steroids (Medrol Dosepak) by Dr. Roy on April 12, 2017. When Petitioner returned to see Dr. Roy on April 24, Petitioner reported that he took the antibiotics and steroids but they did not improve his symptoms. While Ciorba et al. suggests that only 14% of patients with AIED are responsive to steroids, Petitioner's failure to improve on steroids weighs against finding that his hearing loss was autoimmune in nature. Pet. Ex. 18-9 at 3; see also Pet. Ex. 18-11 at 1 ("AIED is one of the few forms of sensorineural deafness that can potentially be treated."); Pet. Ex. 18-8 at 8 ("A positive response to [steroid] therapy is the third criterion for the diagnosis of [AIED].").

None of Petitioner's records in 2017 reference any autoimmune hearing loss. None of Petitioner's treating physicians suggest that the hearing loss was autoimmune in nature. Great weight is afforded to contemporaneous records is due to the fact that they "contain information

supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” Cucuras, 993 F.2d at 1528; see also Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326.

While Dr. Karadsheh and Dr. Roy later opined Petitioner experienced some kind of abnormal immune response, the undersigned finds these opinions less persuasive for two main reasons. First, Dr. Roy’s opinions were not made contemporaneously. See Zumwalt v. Sec’y of Health & Hum. Servs., No. 16-994V, 2019 WL 1953739, at \*19 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (rejecting opinion from a treating provider when he presented an opinion two-and-one-half years after treatment and after litigation was initiated), mot. for review den’d, 146 Fed. Cl. 525 (2019); Vergara v. Sec’y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at \*4 (Fed. Cl. Spec. Mstr. May 15, 2014) (“Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.”). Second, neither Dr. Roy nor Dr. Karadsheh provided any support or evidence for their opinions. Moreover, there is no evidence to support that an abnormal immune response equates to an autoimmune condition.

Because AIED is a difficult diagnosis to make, Sakano and Harris advised that “the presence of additional systemic autoimmune findings, diagnosis of autoimmune disorder, or laboratory findings of autoimmune markers may aid in the diagnosis” of AIED. Pet. Ex. 19-5 at 1. Petitioner’s physicians did not order diagnostic testing for an autoimmune condition. Laboratory tests to diagnose AIED (an autoimmune condition) include C-reactive protein, ANA, ANCA, and a host of other tests<sup>73</sup> that were not done on Petitioner. This suggests that Petitioner’s physicians did not suspect that his hearing loss was autoimmune in nature. Regardless of the reason that such tests were not ordered, there is no factual support for a finding that Petitioner had any systemic autoimmune findings, as there are none in his medical records or the evidence filed in this case.

The low pneumococcal antibody titers discussed by the parties do not constitute autoimmune markers. Instead, Dr. Whitton opines they merely reflect the levels of antibodies against 23 bacterial polysaccharides and can be used to show an appropriate response to vaccination. Resp. Ex. A at 8. This is addressed further in the prong two analysis.

Additionally, the undersigned notes that another Vaccine Program case has addressed the question of an AIED diagnosis, and the special master determined there was not preponderant evidence to support the diagnosis. Henry v. Sec’y of Health & Hum. Servs., No. 17-721V, 2022 WL 2301321, at \*1 (Fed. Cl. Spec. Mstr. May 2, 2022). Like here, in Henry, the Petitioner’s expert suggested the correct diagnosis was AIED and Respondent’s experts disagreed. Id. at \*11, \*20-21. The special master found that Petitioner’s hearing loss was not progressive (the first audiogram seven months after vaccination showed “bilateral normal sloping to mild mid frequency SNHL,” and a follow-up audiogram one year later was essentially unchanged); Petitioner’s laboratory studies were not supportive of AIED; and her physicians did not diagnose her with AIED. Id. at \*29-31. While the facts are not directly on point with those here, the

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<sup>73</sup> For a complete list by Ciorba et al., see Pet. Ex. 18-9 at 4 tbl.2.

reasons for the special master's findings are similar to the undersigned's. The undersigned agrees with the reasoning by the special master in Henry and finds it supportive here.

For these reasons, the undersigned finds Petitioner has not proven by preponderant evidence that he has AIED.

## V. CAUSATION ANALYSIS

### A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009); Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable" medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 214, 257 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If Petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen, 618 F.3d at 1347 ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The undersigned finds Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the flu and/or Prevnar 13 vaccines can cause hearing loss. There are several reasons for this finding.

At the outset, the undersigned notes that Dr. Beck's opinions are somewhat confusing and like his diagnosis opinions, he fails to adequately explain his causation theory. Moreover, Dr. Beck seems to suggest there are two theories at play, an immune-mediated mechanism (or abnormal immune response) and an immunodeficiency theory. And sometimes Dr. Beck appears to combine the two theories. Piecing together his opinions, it appears Dr. Beck's theory is that Petitioner had an abnormal immunologic response or immunodeficiency following the vaccinations which was responsible for triggering AIED. As such, Petitioner's theory relies on the presumptions that (1) the vaccines induced an abnormal immune response or immunodeficiency in Petitioner and (2) that Petitioner has AIED. Because there is not preponderant evidence that Petitioner's diagnosis is AIED, to the extent Petitioner's theory relies on this factual presumption, Petitioner's causal theory fails.<sup>74</sup> The undersigned addresses the immunodeficiency theory below in the prong two analysis.

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<sup>74</sup> The undersigned's ruling as to diagnosis is not determinative as to Althen prong one. There are independent reasons that the undersigned finds Petitioner has failed to prove Althen prong one as explained herein.

Regarding Dr. Beck's purported immune-mediated theory, the undersigned finds it is not well developed. He states that "[i]mmune-mediated mechanisms activate the innate immune system within the inner ear and thereby produce antigens which are known to cause damage to the cochleovestibular structures." Pet. Ex. 18 at 11. Dr. Beck does not explain this theory; he does not explain how or what immune-mediated mechanisms activate, how the immune system is activated in the inner ear, what antigens are produced, or how it all connects.

Petitioner need not make a specific type of evidentiary showing or require identification of a specific antigenic trigger for an immune-mediated pathology to prove that a theory is sound and reliable by preponderant evidence. Given the state of current scientific knowledge, there is no way that a petitioner could satisfy such a requirement. Requiring proof of the identify of a specific antigen to prove causation would require scientific certainty, which is a bar too high. See Knudsen, 35 F.3d at 549 (explaining that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program").

However, based on the current understanding of immune-mediated hearing loss as described in the literature filed herein, Dr. Beck's proposed mechanism falls short of sound and reliable, is conclusory in nature, and vague.

First, the medical literature consistently reports that the causal mechanism of AIED is unknown. See, e.g., Pet. Ex. 19-5 at 2 ("It is not known what triggers the autoimmune response" in AIED.); Pet. Ex. 18-9 at 5 ("The inflammatory and the immune-mediated pathogenetic mechanisms [of AIED] are still not completely known . . ."); Pet. Ex. 18-10 at 2 ("A wide variety of antibodies against different ear tissues have been detected. However, the recognition of multiple antigens did not identify any one as being the specific target in [AIED]."); Pet. Ex. 18-11 at 2 ("The pathogenesis of bilateral, progressive, fluctuating hearing loss is unknown . . ."). Further, the causal mechanism of SNHL, a component of AIED, also remains unknown. See, e.g., Resp. Ex. A, Tab 8 at 4 ("The etiology of most cases of [sudden SNHL] is unknown."); Resp. Ex. C, Tab 3 at 1 ("Despite continuous efforts to clarify the pathophysiological characteristics [of SNHL], the cause remains largely unclear with approximately 90% of cases being idiopathic."); Pet. Ex. 18-6 at 1, 5 ("The precise cause of sudden [SNHL] has not been identified," and "[m]ost patients with sudden [SNHL] cannot be given a cause for their diagnosis.").

Dr. Beck cites literature discussing viral infection as a trigger for immune-mediated hearing loss, but this literature does not contemplate vaccination as a trigger via the same process. For example, Schreiber et al. noted several viruses that have been "postulated as possible causes" of sudden SNHL such as mumps, rubella, varicella zoster virus, flu virus, cytomegalovirus, Epstein-Barr virus, and herpes simplex virus. Pet. Ex. 18-6 at 2. The authors did not discuss vaccination. Chen et al. explained that a systemic or distant viral infection can trigger an antibody response "that cross-reacts with an inner ear antigen . . . or that triggers a circulating ligand, causing pathologic activation of cellular stress pathways within the cochlea." Pet. Ex. 18-3 at 2. The authors also did not discuss vaccination. Dr. Beck does not explain how this would translate to vaccination as a trigger for immune-mediated hearing loss.

Moreover, Petitioner's case reports of hearing loss associated with vaccination generally involve the mumps and/or measles, tetanus, and rabies vaccinations, live virus vaccines which Petitioner did not receive. Therefore, the relevance of these case reports is unclear as case reports about one vaccine cannot automatically be imputed to a different vaccine, particularly when the mechanism offered has not been suggested as to the vaccine at issue. "An expert may 'extrapolate from existing data,' and use 'circumstantial evidence,' [b]ut the reasons for the extrapolation should be transparent and persuasive." K.O. v. Sec'y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at \*12 (Fed. Cl. Spec. Mstr. July 7, 2016) (internal citations omitted) (first quoting Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009); and then quoting Althen, 418 F.3d at 1280).

Here, Dr. Beck does not explain how data from other unrelated vaccines could be extrapolated to the vaccines at issue here and accordingly, is not persuasive. See K.O., 2016 WL 7634491, at \*12 (finding the case reports offered by Petitioner as having even less value than case reports do generally because they reported a sequence in which a vaccine, but not the vaccine at issue, preceded the onset of the injury at issue (citing Campbell v. Sec'y of Health & Hum. Servs., 97 Fed. Cl. 650, 668 (2011))); Crosby v. Sec'y of Health & Hum. Servs., No. 18-1478V, 2021 WL 3464125, at \*9 (Fed. Cl. Spec. Mstr. July 22, 2021) (declining to give substantial weight to an article because it was on a different vaccine than the one at issue making reasoning difficult); see also Deshler v. Sec'y of Health & Hum. Servs., No. 16-1070V, 2020 WL 4593162, at \*19-21 (Fed. Cl. Spec. Mstr. July 1, 2020) (declining to attribute case reports on the flu vaccine to pneumococcal vaccines); McDonald v. Sec'y of Health & Hum. Servs., No. 15-612V, 2023 WL 2387844, at \*23 (Fed. Cl. Spec. Mstr. Mar. 7, 2023).

Dr. Beck does cite Huang et al., in which "a causal connection was speculated between the [2009-2010] H1N1 vaccination and the development of bilateral sudden hearing loss 14 hours later;" however, the exact cause could not be identified. Pet. Ex. 18-2 at 2. The authors discussed sudden deafness following the administration of other vaccines such as tetanus antitoxin, whooping cough, rabies, mumps, and hepatitis B vaccines. In those cases, the "causative factors of deafness were considered to be the viral components of the vaccines . . . or the latent autoimmune response to the vaccine contents." Id. at 2. The H1N1 vaccine subject to Huang et al. did not contain a live virus, and the authors did not discuss the viral components as causative factors. Likewise, the vaccines Petitioner received did not contain live viruses, and Dr. Beck does not discuss the viral components or the contents of the vaccines at issue here.

Overall, the undersigned finds that here, Petitioner's immune-mediated theory is unsupported by medical or scientific facts, research, or any other reliable evidence. Moreover, his theories are speculative and/or conclusory in nature. When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at \*31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. den'd, decision aff'd, 141 Fed. Cl. 138, aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at \*19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592



F.3d at 1315). Instead, special masters are expected to carefully scrutinize the reliability of each expert report submitted. See id.

Both of Respondent's experts filed Baxter et al. which is applicable as it relates to the flu vaccine. They studied whether there was an association between vaccination and sudden SNHL by looking at first time diagnoses of sudden SNHL from 2007 through 2013. During this time, more than 20 million vaccines were administered, including more than eight million inactivated flu vaccines. The authors "found no increased risk of prior [trivalent inactivated flu] vaccination in patients with [sudden SNHL] in any of the prespecified risk intervals." Resp. Ex. A, Tab 8 at 3. There were no references filed analyzing the Prevnar 13 vaccine and hearing loss.

While Frenck et al. noted that "[m]ore systemic adverse events were seen with the concomitant administration of [Prevnar 13] and [trivalent inactivated flu vaccine] than with the single administration of either vaccine," the authors posited that "[g]iven that the two vaccines were administered concomitantly, the higher rate of systemic events does not appear to be unusual and is not considered clinically meaningful." Resp. Ex. C, Tab 4 at 7. Importantly, this specific part of the article was discussing local site reactions as adverse reactions, not hearing loss as adverse events. Hearing loss was not discussed at all in the article.

Lastly, there are several other Vaccine Program cases with reasoned decisions regarding numerous causation theories for hearing loss, and the special masters in those cases often denied entitlement. While the mechanisms and vaccines may differ,<sup>75</sup> SNHL and AIED have been rejected as a vaccine-related injury due to insufficient evidence to support causation. Although decisions of other special masters are not binding, the undersigned generally agrees with the reasoning of her colleagues in these cases. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

Like the causation theory here, Petitioner's theory in Henry, was found lacking. Henry, 2022 WL 2301321, at \*32. Petitioner's expert proposed that a "subclinical viral infection initiated an IgM antibody response causing cross-reactivity between the virus and the auditory nerve" and that "flu vaccination accelerated this immune response via bystander activation." Id. Petitioner's expert mentioned molecular mimicry but in connection to the viral infection and did not connect it to AIED. Id. at \*32-33. The special master found Petitioner did not have a viral infection at the time of vaccination therefore "eliminate[ing] a critical step in [Petitioner's] causation theory." Id. at \*26-29, \*33. The special master reasoned, "[i]f there was no viral infection, then there was no initial production of autoantibody which cross reacted with a component of her viral infection." Id. at \*33 (internal quotations omitted). Respondent's expert also filed Baxter et al. which the special master found applicable and persuasive. Id. The proffered mechanism in Henry was more well developed than Petitioner's theory here but was still insufficient to establish causation.

Next, the Petitioner in Inamdar alleged the flu vaccine caused his SNHL. Inamdar v. Sec'y of Health & Hum. Servs., No. 15-1173V, 2019 WL 1160341, at \*1 (Fed. Cl. Spec. Mstr.

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<sup>75</sup> The undersigned notes that there are no reasoned decisions involving the Prevnar 13 vaccine and hearing loss.



Feb. 8, 2019). Petitioner proposed the flu vaccine “could cause the production of proinflammatory cytokines immediately upon vaccine administration,” and alternatively, that specific components of the vaccine “were structurally homologous with ganglioside receptors on the neuronal myelin contained in the inner ear tissue, and that antibodies generated in response to the vaccine could also cross-react with the self-myelin, resulting in tissue damage.” Id. at \*5-6. The Chief Special Master found the first theory relied too heavily on what was known about the wild virus rather than the vaccine, and further found that both theories were unsupported by the literature. Id. at \*17-18. An alternative cause also existed, and a one-day onset was not shown to be medically acceptable. Id. at \*18-19; see also Donica v. Sec’y of Health and Hum. Servs., No. 08-625V, 2010 WL 3735707, at \*8 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (denying entitlement where the proposed theory was that the flu vaccine induced “an immune response to the viral particles in the inner ear” or alternatively “activated other live viruses within the inner ear”).

Similarly, in Doe/16, Petitioner’s expert proposed an autoimmune hypersensitivity reaction theory for how the flu vaccine can cause sudden SNHL. Doe/16 v. Sec’y of Health & Hum. Servs., No. 06-670V, 2008 WL 2390064, at \*5 (Fed. Cl. Spec. Mstr. June 2, 2008). Petitioner’s expert “did not believe the killed virus in the vaccine could directly provoke an illness,” rather that the flu vaccine “triggered an antigen reaction, which caused inflammation” in the endolymphatic sac. Id. The special master found the medical literature lacked support for the autoimmune hypersensitivity reaction, and the timing was too short. Id. at \*12-14.

Hopkins discussed how SNHL could not be caused by multiple vaccines<sup>76</sup> based on a theory of an autoimmune reaction resulting from an environmental trigger. Hopkins v. Sec’y of Health & Hum. Servs., No. 00-745V, 2007 WL 2454038, at \*1, \*19-23 (Fed. Cl. Spec. Mstr. Aug. 10, 2007), aff’d, 84 Fed. Cl. 517 (2008). In addition to the submitted literature failing to support that theory, the special master also considered the fact that none of the treating physicians believed the vaccinees suffered an autoimmune process. Id. at \*21. The temporal relationship and evidence of a genetic cause were also at issue. Id. at \*18-20.

In Kelly, the Petitioner alleged the flu vaccine caused his SNHL. Kelly v. Sec’y of Health & Hum. Servs., No. 16-878V, 2021 WL 5276373, at \*1 (Fed. Cl. Spec. Mstr. Oct. 18, 2021), mot. for review den’d, 160 Fed. Cl. 316 (2022). Petitioner alleged a significant aggravation claim, but the Chief Special Master noted his determination would have been the same even if Petitioner alleged a causation-in-fact claim. Id. at \*24. Petitioner proposed a Type I sensitivity reaction and alternatively, an autoimmune response. Id. at \*25-26. The Chief Special Master found limited support for the primary theory and found the autoimmune theory inconsistent with the facts presented, including the fact that Petitioner’s hearing loss was unilateral, and the onset was two hours. Id. at \*24-26. It was also noted that “an autoimmune origin would in most cases mean some other underlying systemic disease was occurring” and there was nothing in the record to support that. Id. at \*26 (emphasis omitted).

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<sup>76</sup> The vaccines at issue in Hopkins were haemophilus influenzae type B, diphtheria-tetanus-pertussis, and oral polio. Hopkins v. Sec’y of Health & Hum. Servs., No. 00-745V, 2007 WL 2454038, at \*1, \*19-23 (Fed. Cl. Spec. Mstr. Aug. 10, 2007), aff’d, 84 Fed. Cl. 517 (2008).

While there is one reasoned decision where entitlement was granted to a petitioner who alleged the flu vaccine caused sudden SNHL, the undersigned notes that the facts and theory here are different. Madigan v. Sec’y of Health & Hum. Servs., No. 14-1187V, 2021 WL 3046614, at \*1 (Fed. Cl. Spec. Mstr. June 25, 2021). In Madigan, the Petitioner proposed a stress response theory which “suggests that stress leaves people susceptible to immune disruption both by reducing natural killer (‘NK’) cells, which help resist viral and bacterial infection, and by promoting production of proinflammatory cytokines IL-1 and IL-6.” Id. at \*12.

In summary, Petitioner has failed to offer a sound and reliable medical theory in support of his claim. Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the first Althen prong.

## **B. Althen Prong Two**

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). While the medical records and opinions of treating physicians must be considered, they are not binding on the special master. § 13(b)(1)(B) (specifically stating that the “diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”).

Since Petitioner failed to prove Althen prong one, it follows that he cannot prove Althen prong two. However, even if Petitioner had proven Althen prong one, the undersigned finds Petitioner has failed to show by preponderant evidence that there is a logical sequence of cause and effect showing Petitioner’s flu and/or Prevnar 13 vaccines caused his hearing loss.

First, regarding Dr. Beck’s opinions that seem to relate to an abnormal immune response, he relies on Petitioner’s laboratory results, but Petitioner’s results were normal.

Petitioner was tested for IgA, IgM, IgG, mumps antibodies, and pneumococcal antibodies. IgA, IgM, and IgG were normal. Dr. Whitton persuasively explained that Petitioner’s Ig showed that he had a normal immune response. Further, mumps IgG was positive and mumps IgM was negative, showing either a previous mumps infection or mumps vaccine. Several of the pneumococcal antibodies were low. But the reasons were explained by Dr.

Whitton, and the results do not support any finding that Petitioner had any immunodeficiency. Moreover, Petitioner's treating physicians did not diagnose him with any immunodeficiency.

Dr. Beck opines the lab testing "indicated a marked abnormal immune system response as multiple pneumococcal antibody subtypes were abnormally low despite the previous administration of Prevnar 13 vaccination on [October 22, 2016]." Pet. Ex. 18 at 6. Dr. Beck does not explain the lab results beyond this and does not explain how the low pneumococcal antibodies indicate an immunodeficiency or an abnormal immune response. Dr. Beck does not refute the opinions by Respondent's experts and maintains his position that Petitioner's lab results demonstrate an "abnormal immunologic response" despite opinions to the contrary. See Pet. Ex. 19 at 16.

Relevant to this point, Dr. Beck is not an immunologist but an ENT specialist. Dr. Roy and Dr. Bigelow are also ENT specialists. Additionally, Petitioner, who himself offered opinions on his immunodeficiency, is trained in internal medicine, hematology, oncology, and hyperbaric medicine, but not immunology. Finally, Dr. Karadsheh, Petitioner's colleague from Jordan, is a consultant physician in allergy and immunology. While no curriculum vitae was filed, his title indicates he has immunology training, however, it is not clear from his email what records he reviewed, and he did not explain any reasoning for his opinions. Thus, his opinions hold less weight than Dr. Whitton, a qualified immunologist. See Locane v. Sec'y of Health & Hum. Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012) (affirming the special master's finding that one expert's testimony was more persuasive than another's "because of their different backgrounds and specialties"); Pafford, 451 F.3d at 1359 (affirming the special master's rejection of expert's testimony because he lacked proper qualifications in the specialty areas in which he testified); Dwyer v. Sec'y of Health & Hum. Servs., No. 03-1202V, 2010 WL 892250, at \*64 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (giving greater weight to M.D. epidemiologists' opinions on medical issues than to Ph.D. epidemiologist's opinion).

In summary, Dr. Karadsheh, Petitioner, Dr. Roy, and Dr. Beck opine that the simultaneous administration of flu and Prevnar 13 vaccines may have induced a state of immunodeficiency. But they did not provide support for this opinion. They did not define immunodeficiency. They did not explain how the vaccines could cause Petitioner to become immunodeficient, and they did not explain how such immunodeficiency could cause AIED or SNHL.

While Dr. Roy opined in his 2018 declaration that the vaccines Petitioner received caused an "immune deficiency," this was not documented in Dr. Roy's contemporaneous medical records. Pet. Ex. 7 at ¶ 6. In his records, Dr. Roy did not document any immune deficiency, that it was caused by vaccines, or that it led to hearing loss.

The undersigned finds no evidence that Petitioner had an immunodeficiency or an abnormal immune response. As such, this aspect of Petitioner's case is without any factual foundation and is therefore speculative. When evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck, 2018 WL 3679843, at \*31.

Next, the undersigned finds that while some of Petitioner's treating physicians documented his reports of symptoms and/or their temporal association with vaccination,<sup>77</sup> they did not opine that his vaccines caused his hearing loss.

Treating physician statements are typically "favored" as treating physicians "are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67. "As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at \*8 (Fed. Cl. Spec. Mstr. July 2, 2019).

On April 12, 2017, Petitioner first presented to his treating ENT specialist, Dr. Roy, who wrote that Petitioner "developed the flu and a severe URI in December and ever since then[,] [Petitioner] had bilateral ear pain and hearing loss." Pet. Ex. 4 at 1. Dr. Roy diagnosed him with "bilateral mucoid otitis media after the flu." Id. at 3. On April 24, 2017, Dr. Roy wrote that Petitioner had "chronic tinnitus and conductive hearing loss after developing an illness after a flu and [Prevnar 13] vaccine." Id. at 6.

The opinions of Dr. Roy in April 2017 only appear to show the sequence of events: that Petitioner received the vaccines, he subsequently had an illness in December, and thereafter he developed conductive hearing loss. He subsequently offered a conclusory causal opinion. Dr. Roy opined in his 2018 declaration that the vaccines Petitioner received "were a substantial factor in causing an immune deficiency that resulted in [Petitioner's] upper respiratory symptoms and consequential . . . hearing loss." Pet. Ex. 7 at ¶ 6.<sup>78</sup>

However, several factors lead the undersigned to give Dr. Roy's causal opinion in his declaration less weight than what Petitioner might urge. First, no contemporaneous treater, other than Dr. Roy, seemed to consider that Petitioner's hearing loss was a vaccine-related injury to corroborate Dr. Roy's opinion.<sup>79</sup>

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<sup>77</sup> For example, Dr. Hoang wrote that Petitioner "[r]eport[ed] he had hearing loss that started after [flu] and [Prevnar 13] vaccine in 2016." Pet. Ex. 20 at 17. Not only does this note solely reflect temporal association, but it was also Petitioner's recollection, not Dr. Hoang's findings.

<sup>78</sup> The undersigned again notes that the contemporaneous medical records by Dr. Roy do not mention an abnormal immune response or immune deficiency.

<sup>79</sup> Nurse Adorador noted hearing loss and "[p]er [Petitioner], [it was] secondary to flu vaccine given several years ago." Pet. Ex. 16 at 3. But again, this is Petitioner's opinion as reported to Nurse Adorador. Dr. Arruda documented that "[t]he issue with infection and hearing loss apparently related to a flu vaccine and [Prevnar 13] vaccine." Pet. Ex. 21 at 6. However, this was more than five years after the date of vaccinations.

Second, Dr. Roy's causality views only came into focus in June of 2018—one-and-one-half years after Petitioner first presented to Dr. Roy and were in preparation for litigation.<sup>80</sup> It is well-established in the Vaccine Program that contemporaneous medical records are given more weight than later-in-time statements to the contrary. See Burns, 3 F.3d at 417 (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is “uniquely within the purview of the special master”); Zumwalt, 2019 WL 1953739, at \*19; Vergara, 2014 WL 2795491, at \*4. The greater weight afforded to contemporaneous records is due to the fact that they “contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” Cucuras, 993 F.2d at 1528; see also Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326; Ricci v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 385, 391 (2011) (“Medical records from years later, merely chronicling a timeline between vaccination and injury, are not worthy of the same consideration as contemporaneous records.”).

Here, the contemporaneous records do not contemplate vaccine causation.<sup>81</sup> Dr. Roy's subsequent opinion that Petitioner's vaccinations were a substantial factor in causing an immune deficiency, and consequentially hearing loss, therefore loses some of its probative weight when considered in light of the full medical record. Because the declaration by Dr. Roy in June 2018 is different than his earlier-in-time medical records on several occasions, the undersigned finds the earlier records are more reliable and consistent with the rest of the records.

Lastly, Respondent's experts offer opinions as to alternate causes for Petitioner's hearing loss, namely his poorly controlled diabetes. Dr. Whitton opines Petitioner's diabetes was poorly controlled as evidenced by his high HbA1c levels and cites medical literature to support an association and increased risk between diabetes, especially when poorly controlled, and hearing loss. The undersigned acknowledges that Petitioner is not required to eliminate other potential causes in order to be entitled to compensation. See Walther v. Sec’y of Health & Hum. Servs., 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (finding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, she finds it reasonable to consider “evidence of other possible sources of injury” to determine “whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.” Stone, 676 F.3d at 1379; see also Winkler v. Sec’y of Health & Hum. Servs., 88 F.4th 958, 963 (Fed. Cir. 2023) (finding that the special master's “contemplation of a potential causative agent when evaluating whether or not a petitioner has established a prima facie case is in accordance with the law”).

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<sup>80</sup> Dr. Roy's declaration was executed in 2018. While Petitioner's case was not filed until 2019, Dr. Roy's declaration has the case caption on the document and therefore indicates it was intended for litigation. Moreover, on May 10, 2017, Petitioner reported that he was “currently in an open case due to side effects of vaccines from flu shot” further providing evidence that Dr. Roy's 2018 declaration was obtained for purposes of litigation. Pet. Ex. 3 at 48.

<sup>81</sup> As a reminder, Dr. Karadsheh is not one of Petitioner's treating physicians.



The fact that Petitioner had diabetes—and that his HbA1c levels were high in the months preceding and following the vaccinations—“makes it difficult to attribute ‘but for’ causation to the vaccination.” Pafford, 451 F.3d at 1358-59; see also Walther, 485 F.3d at 1151 n.4 (“Where multiple causes act in concert to cause the injury, proof that a particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine.”). However, the undersigned does not find, nor does Respondent argue, that the evidence is sufficient to establish, more likely than not, that diabetes was the cause of Petitioner’s hearing loss.

For all these reasons, the undersigned finds that Petitioner failed to provide preponderant evidence of a logical sequence of cause and effect. Thus, Petitioner has failed to satisfy Althen prong two.

### C. Althen Prong Three

Althen prong three requires Petitioner to establish a “proximate temporal relationship” between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That phrase has been defined as a “medically acceptable temporal relationship.” Id. A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; see also Koehn v. Sec’y of Health & Hum. Servs., 773 F.3d 1239, 1243-44 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542. Thus, prong three contains two parts. First, Petitioner must establish the “timeframe for which it is medically acceptable to infer causation” and second, they must demonstrate that the onset of the disease occurred in this period. Shapiro, 101 Fed. Cl. at 542-43.

Because Althen prong three coincides with Althen prong one, Petitioner’s inability to meet his burden demonstrating how the flu and/or Prevnar 13 vaccines can cause hearing loss effectively precludes him from being able to meet his burden under the third Althen prong.<sup>82</sup> Thus, because the undersigned found that Petitioner did not offer a sound and reliable theory of causation, he cannot demonstrate that his condition arose in a medically acceptable timeframe pursuant to that theory. Even assuming that Petitioner satisfied Althen prong three, that alone would not satisfy Petitioner’s overall burden of proof. Veryzer v. Sec’y of Health & Hum. Servs., 100 Fed. Cl. 344, 356 (2011) (explaining that a “temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury.”). However, Petitioner’s showing with respect to the third Althen prong is deficient.

The parties stipulated that Petitioner received the flu and Prevnar 13 vaccines on October 22, 2016, and about one week later, Petitioner developed URI symptoms and then noticed

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<sup>82</sup> There are independent reasons that the undersigned finds Petitioner has failed to prove Althen prong three as explained herein.



problems hearing.<sup>83</sup> Joint Submission at 2 (citing Pet. Ex. 1 at ¶ 7; Pet. Ex. 2 at 1). The undersigned agrees that Petitioner's hearing loss occurred after the vaccinations. But whether it occurred in an appropriate timeframe given the theories presented is a different question that Petitioner failed to provide answers to.

Dr. Beck opines that because Petitioner developed symptoms one week after his vaccinations, it is therefore within the medically acceptable timeframe of three to 90 days for AIED. However, this is the timeframe for the progression of AIED, not the timeframe for the onset of the disease. Dr. Beck does not offer any opinions on the medically acceptable timeframe for his theories based on an abnormal immune response or immunodeficiency basis.

Because Petitioner does not offer a medically acceptable timeframe for immune-mediated hearing loss, Petitioner cannot demonstrate that the onset of his disease occurred during such timeframe. Moreover, Dr. Beck referred to Petitioner's hearing loss as both sudden and progressive but did not address how an onset of one week is consistent with either of these characteristics.

Further, as explained by Dr. Bigelow, the initial audiograms performed six months after vaccination showed predominantly conductive hearing loss. Petitioner did not have evidence of SNHL, which is associated with AIED, until March 2019, well over two years after his vaccinations. Dr. Bigelow opined that because Petitioner's deterioration of the left-sided SNHL occurred between one and three years after vaccinations, there is no temporal association between the vaccinations and SNHL. The undersigned finds Dr. Bigelow's opinions based on the audiogram results to be persuasive.

Accordingly, the undersigned finds Petitioner failed to provide preponderant evidence of Althen prong three.

## VI. CONCLUSION

The undersigned extends her sympathy to Petitioner for his condition. The undersigned's Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that flu vaccine and/or Prevnar 13 vaccine he received caused his hearing loss. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

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<sup>83</sup> Although the parties stipulated that about one week after the vaccinations Petitioner developed URI symptoms and then noticed problems hearing, Dr. Bigelow opines that Dr. Roy's medical records suggest that Petitioner's ear symptoms and hearing loss did not began until "sometime in December 2016 which would be somewhere between [six] and 10 weeks after the vaccination." Resp. Ex. C at 16.

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**

Nora Beth Dorsey  
Special Master